SIEMENS

SONOLINE Antares
Ultrasound Imaging System
Transducer Reference

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Siemens Medical Solutions USA, Inc.

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SONOLINE Antares Ultrasound Imaging System Transducer Reference

Software Version 2

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CE Declaration

This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices. Siemens Medical Solutions USA, Inc., is certified by notified body 0123 to Annex II.3 – Full Quality System.

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About This Manual

The user and reference manuals for this product include the following:

The *Instructions for Use* provides instructions on caring for, maintaining, cleaning, disinfecting, and using the ultrasound imaging system. The *Instructions for Use* also contains information on caring for, cleaning, disinfecting, and storing transducers and their accessories.

The *System Reference* provides information regarding the ultrasound imaging system. It is organized by the following categories: *Image, Calcs, Patient Data,* and *Resources.*

The *Transducer Reference* provides acoustic power intensities and mechanical and thermal index (MI/TI) information for the transducers compatible with the ultrasound imaging system.

Conventions

Conventions used throughout this manual are listed below. Take a moment to familiarize yourself with these conventions.

Warnings, Cautions, and Notes

⚠ **WARNING:** Warnings are intended to alert you to the importance of following the correct operating procedures where risk of injury to the patient or system user exists.

⚠ **Caution:** Cautions are intended to alert you to the importance of following correct operating procedures to prevent the risk of damage to the system.

Note: Notes contain information concerning the proper use of the system and/or correct execution of a procedure.

Control Panel Keys and Controls

Controls and keys located on the control panel are identified by uppercase boldface type.

Example: Rotate the **MENU** control.

Keys located on the keyboard are identified by boldface type.

Example: Press the **Patient** key located on the keyboard.

On-Screen Objects

On-screen objects such as task card tabs, menu selections, buttons, entry fields, names of forms and dialogs, and group boxes are identified by boldface type.

Example: The system displays the **Image** task card.

Selection of On-Screen Objects

The **SELECT** key on the control panel functions as a point-and-select device when used with the trackball (similar to a computer mouse). To select an on-screen object (such as a task card tab or a button), roll the trackball to position the pointer (cursor) on the object and then press the **SELECT** key on the control panel.

Special Terms

Special terms are indicated in boldface italicized text and are accompanied by a brief description on their first use in the manual.

Example: When the trackball is used to make menu selections, it is assigned to the ***pointer*** function.

Cross References

When additional information exists within this or other manuals, a reference graphic and the name of the book is provided in the right column. If the information exists within the chapter, a cross-reference to the page number is listed. Otherwise, information is referenced by topic and chapter number. The *System Reference* organizes information by category, topic, and chapter number.

In the **System Reference** example, Image and Resources are categories; Imaging and Accessories and Options are topics; Ch 1 and Ch 2 are chapter numbers.

Transducer Reference

Acoustic Tables	Ch 1

Instructions for Use

System Controls	Ch 3

System Reference

IMAGE:	
Imaging	Ch 1
RESOURCES:	
Accessories and Options	Ch 2

System Presets

You can use the options and settings available in the system presets menu to set up the ultrasound system with your preferences. Presets define the configuration of the system software whenever you power on the system.

You can press the **Presets** key on the keyboard or select the **Presets** button on the image screen to access the system **Presets** menu.

A complete listing of system presets is located in the *System Reference*. Whenever a system preset is discussed in other chapters or in the User and Reference Manuals, a graphic is provided in the right column.

The graphic identifies a preset option or setting in the system presets menu that is available for you to customize your ultrasound system. The name of the category on the menu containing the system preset is listed for your convenience.

System-wide
Meas. Tools

Example: Use the system presets to set the number of heart cycles to include between the two vertical lines.

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Transducer Reference

Chapter Title	Chapter Description
Chapter 1 **Acoustic Output Reference**	Acoustic power intensities and MI/TI information.
Chapter 2 **Transducer Accessories**	Attachment instructions for transducer accessories.
Chapter 3 **Specialty Transducers**	Reserved for future use.

Note: Not all features and options described in this publication are available to all users. Please check with your Siemens representative to determine the current availability of features and options.

1 Acoustic Output Reference

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Transducer Technical Data and Acoustic Output

Transducers and Intended Applications

Only the following transducers from Siemens are compatible with the SONOLINE Antares ultrasound imaging system:

EMC Note: (Applies to the transducers indicated by an asterisk (*) while in use with the SONOLINE Antares ultrasound imaging system.) Operating the transducer in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to temporary degradation or interference visible on the monitor screen. A lightening of image background may be noticed while visualizing hypoechoic structures, or color spectral interference, or jitter, or horizontal lines in the image screen may occur. The transducer and the system have been designed and tested to withstand such interference and will not be permanently damaged.

TRANSDUCER NAME	OPERATING FREQUENCY	MODES OF OPERATION	INTENDED APPLICATIONS
CURVED AND LINEAR ARRAY TRANSDUCERS			
*C5-2	2D-mode: 2.5 MHz–5.0 MHz Doppler: 2.0 MHz–4.0 MHz	2D, C, D, M	Abdominal, gynecology, obstetrics, pelvic
CX5-2	2D-mode: 2.5 MHz–5.0MHz Doppler: 2.0 MHz–4.0 MHz	2D, C, D, M	Abdominal, gynecology, obstetrics, pelvic
CH6-2	2D-mode: 3.6 MHz–6.7 MHz Doppler: 2.5 MHz–3.6 MHz	2D, C, D, M	Abdominal, gynecology, obstetrics
*VF7-3	2D-mode: 3.0 MHz-7.0 MHz Doppler: 3.0 MHz-6.0 MHz	2D, C, D, M	Small parts, vascular, musculoskeletal, gynecology, obstetrics, pelvic, and fetal echo
*VFX9-4	2D-mode: 4.0 MHz-9.0 MHz Doppler: 4.0 MHz-7.0 MHz	2D, C, D, M	Small parts, breast, vascular, musculoskeletal, orthopedics, gynecology, obstetrics, pelvic, and fetal echo
*VF10-5	2D-mode: 5.0 MHz-10.0 MHz Doppler: 4.0 MHz-7.0 MHz	2D, C, D, M	Small parts, breast, vascular, musculoskeletal
*VF13-5	2D-mode: 7.0 MHz-12.0 MHz Doppler: 5.0 MHz-9.0 MHz	2D, C, D, M	Small parts, breast, vascular, superficial musculoskeletal
*VFX13-5	2D-mode: 7.0 MHz-12.0 MHz Doppler: 5.0 MHz-9.0 MHz	2D, C, D, M	Small parts, breast, vascular, superficial musculoskeletal

TRANSDUCER NAME	OPERATING FREQUENCY	MODES OF OPERATION	INTENDED APPLICATIONS
PHASED ARRAY TRANSDUCERS			
P10-4	2D-mode: 4.4 MHz–8.0 MHz Doppler: 4.4 MHz–5.7 MHz	2D, C, D, M	Pediatric, neonatal cephalic
PH4-1	2D-mode: 2.2 MHz–4.0 MHz Doppler: 2.0 MHz–3.3 MHz	2D, C, D, M	Abdominal, gynecology, obstetrics
ENDOCAVITY TRANSDUCERS			
*EC9-4	2D-mode: 3.6 MHz–8.0 MHz Doppler: 3.0 MHz–7.0 MHz	2D, C, D, M	Endocavity

Display Resolution and Measurement Accuracy

When a transducer is capable of exceeding a mechanical or thermal index of 1.0, the imaging system displays indices starting from 0.4 in increments of 0.1 for all displayed values.

Note: A number of factors contribute to the estimation error for the displayed index. Variation among transducers and systems, approximation for real-time index calculations, and measurement errors contribute to the index display error. Measurement precision for acoustic pressure, power, and center frequency is within 6%, 10%, and 2% respectively. The total estimated display accuracy is +/-20% for MI and +/-40% for TI. Definitions for these parameters can be found in the 1998 AIUM/NEMA document entitled *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* – Revision 1 (also known as the Output Display Standard).

Default Displayed MI and TI Values by Transducer

(Per transducer/mode that exceeds default MI or TI value of 0.4)

Transducer	Mode							
	2D		M		pwD		Color	
	MI	TI	MI	TI	MI	TI	MI	TI
C5-2	0.6			0.6		1.6		0.7
CX5-2	0.5			0.5		2.6		1.0
CH6-2	0.6			0.6		3.0		1.2
EC9-4	0.8			0.5		1.3		0.5
P10-4	0.4					2.5		1.2
PH4-1	0.8			0.5		4.2		1.2
VF7-3	1.3					1.6		0.7
VFX9-4	0.8					1.4		1.9
VF10-5	0.9					1.2		1.7
VF13-5	0.8					1.3		2.0
VFX13-5	0.9					1.6		1.4

IEC 61157 Acoustic Output Reporting

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **C5-2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.56	1.74	4.43	1.21	5.38	2.15	4.50	4.50
I_{spta} (mW/cm^2)		14	73	29	216	115	678	347	347
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	2.0	20.0	7.1	24.0	5.0	6.0	4.0	4.0
	Frequency (MHz)	3.08	2.50	2.50	2.22	3.64	2.50	3.08	3.08
I_p (mm)		42	40	34	42	42	43	42	42
W_{pb6} (II) (mm)		4.1	14.6	2.4	39.5	2.0	2.9	1.3	1.3
(⊥) (mm)		3.2	3.0	3.6	2.8	3.4	3.1	3.2	3.2
prr (kHz)						0.1	3.1	0.6	0.6
srr (Hz)		10.8	29.0	5.2	8.0				
Output beam dimensions (II) (mm)		7.1	30.2	16.8	52.1	11.9	14.5	14.4	14.4
(⊥) (mm)		11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2
f_{awf} (MHz)		3.2	2.6	2.5	2.3	3.5	2.5	3.1	3.1
APF [c] (%)		64	131	51	189	42	106	51	51
AIF [d] (%)		64	131	51	189	42	106	51	51
Maximum power (mW)		107	125	50	176	25	78	41	41
I_{ob} (mW/cm^2)		135	37	27	30	19	48	26	26
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **CX5-2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.75	1.81	3.80	1.55	3.55	1.50	4.75	4.02
I_{spta} (mW/cm^2)		14	79	97	273	284	488	285	335
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	4.0	10.0	4.0	20.0	4.0	4.0	4.0	4.0
	Frequency (MHz)	3.08	2.50	2.67	2.22	2.67	2.67	3.08	2.50
I_p (mm)		34	34	30	56	29	29	43	42
W_{pb6} (II) (mm)		2.2	11.7	2.0	37.2	2.1	2.1	1.3	1.5
(⊥) (mm)		3.5	3.6	3.8	3.3	8.6	8.6	3.3	3.3
prr (kHz)						0.4	6.3	0.6	0.6
srr (Hz)		8.3	33.6	5.8	8.9				
Output beam dimensions (II) (mm)		14.2	29.5	9.6	44.9	9.6	9.6	14.2	14.2
(⊥) (mm)		9.0	9.0	9.0	16.0	16.0	16.0	9.0	9.0
f_{awf} (MHz)		3.1	2.7	2.7	2.3	2.7	2.7	3.1	2.7
APF [c] (%)		40	104	50	122	53	126	40	47
AIF [d] (%)		40	104	50	122	53	126	40	47
Maximum power (mW)		146	160	71	225	58	95	36	34
I_{ob} (mW/cm^2)		114	60	83	31	38	62	28	27
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the SONOLINE Antares ultrasound imaging system. Type: **CH6-2**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.90	2.53	5.39	1.96	5.39	2.86	5.30	5.30
I_{spta} (mW/cm^2)		12	105	60	338	210	1137	296	296
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	2.0	14.0	5.0	13.0	5.0	5.0	4.0	4.0
	Frequency (MHz)	4.44	3.64	3.64	2.50	3.64	2.50	3.64	3.64
I_p (mm)		54	45	21	39	44	41	42	42
W_{pb6} (II) (mm)		5.9	13.1	6.1	21.5	1.9	2.3	1.2	1.2
(⊥) (mm)		2.6	3.5	7.2	3.7	4.1	4.1	4.3	4.3
prr (kHz)						0.2	2.4	0.6	0.6
srr (Hz)		27.8	46.6	6.6	9.2				
Output beam dimensions (II) (mm)		7.2	26.7	11.9	31.4	11.9	11.9	14.4	14.4
(⊥) (mm)		12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0
f_{awf} (MHz)		4.5	3.4	3.5	2.6	3.5	2.6	3.5	3.5
APF [c] (%)		65	125	59	162	59	111	60	60
AIF [d] (%)		65	125	59	162	59	111	60	60
Maximum power (mW)		153	200	115	260	70	115	52	52
I_{ob} (mW/cm^2)		177	62	80	69	49	80	30	30
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information for the SONOLINE Antares ultrasound imaging system. Type: **EC9-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.59	2.08	4.68	2.20	6.33	1.85	4.99	4.23
I_{spta} (mW/cm^2)		18	99	78	156	92	1097	346	385
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	1.5	8.0	2.0	11.4	2.0	2.0	2.0	2.0
	Frequency (MHz)	4.71	4.71	5.00	3.64	6.67	5.00	4.71	3.64
I_p (mm)		18	18	17	17	18	23	20	19
W_{pb6} (II) (mm)		0.9	6.0	1.2	9.2	1.1	1.2	1.1	1.3
(⊥) (mm)		1.4	1.4	1.4	1.4	1.3	1.1	1.2	1.3
prr (kHz)						0.1	20.8	1.0	1.0
srr (Hz)		30.2	95.8	6.7	7.8				
Output beam dimensions (II) (mm)		5.5	12.4	4.8	11.2	4.8	4.8	7.4	7.4
(⊥) (mm)		6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
f_{awf} (MHz)		4.8	4.7	4.8	3.7	5.9	5.1	4.7	3.9
APF [c] (%)		74	163	72	154	54	183	68	80
AIF [d] (%)		74	163	72	154	54	183	68	80
Maximum power (mW)		48	30	15	24	4	25	13	11
I_{ob} (mW/cm^2)		144	40	51	36	14	86	29	25
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **P10-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		3.54	2.10	6.06	2.32	6.06	4.10	6.58	6.58
I_{spta} (mW/cm^2)		30	222	83	308	110	950	252	252
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	1.0	5.0	2.5	7.0	2.5	2.5	2.0	2.0
	Frequency (MHz)	4.44	4.44	5.71	4.44	5.71	4.44	6.15	6.15
I_p (mm)		22	20	18	18	20	18	20	20
W_{pb6} (II) (mm)		2.6	4.0	1.2	8.6	1.1	1.3	0.7	0.7
(⊥) (mm)		2.3	2.5	3.3	2.6	2.8	2.7	2.9	2.9
prr (kHz)						0.1	2.2	0.6	0.6
srr (Hz)		19.2	202.9	8.0	15.3				
Output beam dimensions (II) (mm)		3.6	9.4	6.3	13.2	6.2	6.3	7.1	7.1
(⊥) (mm)		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
f_{awf} (MHz)		4.8	4.5	5.7	4.5	5.7	4.5	6.0	6.0
APF [c] (%)		74	126	43	114	44	64	40	40
AIF [d] (%)		74	126	43	114	44	64	40	40
Maximum power (mW)		39	42	20	70	5	43	28	28
I_{ob} (mW/cm^2)		214	88	65	106	18	138	78	78
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **PH4-1**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		4.10	2.20	4.17	1.76	3.26	3.07	4.97	4.97
I_{spta} (mW/cm^2)		14	101	132	208	878	946	271	271
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	2.0	25.0	4.0	12.8	6.0	6.0	4.1	4.1
	Frequency (MHz)	4.00	2.22	3.33	2.00	2.00	2.00	3.64	3.64
I_p (mm)		68	56	23	50	49	49	41	41
W_{pb6} (II) (mm)		10.5	10.1	3.7	15.6	2.5	2.5	1.0	1.0
(⊥) (mm)		4.3	4.6	8.3	4.9	5.5	5.5	6.5	6.5
prr (kHz)						1.6	2.0	0.6	0.6
srr (Hz)		28.5	31.2	6.4	11.5				
Output beam dimensions (II) (mm)		7.1	20.1	10.1	28.2	15.2	15.2	14.5	14.5
(⊥) (mm)		13.5	13.5	13.5	13.5	13.5	13.5	13.5	13.5
f_{awf} (MHz)		3.9	2.3	3.3	2.1	2.1	2.1	3.6	3.6
APF [c] (%)		46	85	45	106	57	61	38	38
AIF [d] (%)		46	85	45	106	57	61	38	38
Maximum power (mW)		69	178	77	240	157	167	41	41
I_{ob} (mW/cm^2)		72	65	57	63	77	81	21	21
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **VF7-3**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		5.62	2.27	6.00	1.81	6.31	3.00	5.62	4.53
I_{spta} (mW/cm^2)		51	244	98	716	98	758	282	317
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	3.0	12.0	3.0	15.5	2.5	2.5	3.0	3.0
	Frequency (MHz)	5.33	3.33	5.33	3.33	5.33	3.33	5.33	3.33
I_p (mm)		26	26	25	29	25	21	29	27
W_{pb6} (II) (mm)		1.2	14.0	1.2	29.1	0.7	1.2	0.9	1.2
(⊥) (mm)		1.2	1.4	1.2	1.5	1.2	1.6	1.1	1.5
prr (kHz)						0.1	4.9	0.6	0.6
srr (Hz)		14.8	21.2	5.9	6.9				
Output beam dimensions (II) (mm)		10.7	27.9	7.1	36.9	9.9	9.9	10.7	10.7
(⊥) (mm)		7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
f_{awf} (MHz)		5.0	3.5	5.2	3.4	5.2	3.4	5.0	3.5
APF [c] (%)		85	209	79	263	76	159	85	105
AIF [d] (%)		85	209	79	263	76	159	85	105
Maximum power (mW)		67	132	33	150	3	23	9	10
I_{ob} (mW/cm^2)		83	63	62	54	3	30	11	12
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information for the SONOLINE Antares ultrasound imaging system. Type: **VFX9-4**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		5.40	4.13	5.16	2.52	6.16	4.57	5.40	4.84
I_{spta} (mW/cm^2)		73	206	54	456	76	890	344	441
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	2.0	3.0	2.0	12.0	2.0	2.0	2.0	2.0
	Frequency (MHz)	5.00	4.00	5.00	4.00	6.67	5.00	5.00	4.00
I_p (mm)		14	14	33	28	18	16	18	15
W_{pb6} (II) (mm)		1.5	3.1	2.0	13.6	0.8	1.1	0.9	1.2
(⊥) (mm)		1.7	1.6	1.9	2.3	1.6	1.7	1.7	1.6
prr (kHz)						0.1	2.0	1.0	1.0
srr (Hz)		62.6	25.8	6.0	6.3				
Output beam dimensions (II) (mm)		7.2	10.8	4.8	28.5	6.6	6.6	7.2	7.2
(⊥) (mm)		4.0	4.0	9.0	9.0	4.0	4.0	4.0	4.0
f_{awf} (MHz)		5.1	4.3	5.0	4.0	6.4	5.0	5.1	4.3
APF [c] (%)		69	91	72	148	61	82	69	77
AIF [d] (%)		69	91	72	148	61	82	69	77
Maximum power (mW)		78	97	39	157	4	16	10	10
I_{ob} (mW/cm^2)		271	225	91	61	15	60	34	35
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the SONOLINE Antares ultrasound imaging system.
Type: **VF10-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		6.29	3.33	6.36	2.65	5.87	4.54	5.64	5.64
I_{spta} (mW/cm^2)		84	370	103	818	495	756	410	410
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	2.0	4.0	1.8	6.0	1.5	1.2	2.0	2.0
	Frequency (MHz)	6.67	5.71	7.27	5.71	7.27	5.71	5.71	5.71
I_p (mm)		14	14	13	14	13	11	17	17
W_{pb6} (II) (mm)		1.8	5.6	1.0	9.8	0.9	1.0	0.8	0.8
(⊥) (mm)		1.3	1.1	1.3	1.1	1.3	1.7	1.1	1.1
prr (kHz)						0.6	1.6	1.0	1.0
srr (Hz)		24.2	46.6	5.7	16.5				
Output beam dimensions (II) (mm)		7.1	14.3	4.2	14.4	3.6	3.0	7.1	7.1
(⊥) (mm)		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
f_{awf} (MHz)		6.6	6.1	7.2	5.8	7.2	5.8	5.9	5.9
APF [c] (%)		75	142	75	179	89	115	84	84
AIF [d] (%)		75	142	75	179	89	115	84	84
Maximum power (mW)		114	127	46	104	18	14	15	15
I_{ob} (mW/cm^2)		318	178	219	144	101	92	43	43
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information for the SONOLINE Antares ultrasound imaging system. Type: **VF13-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	Mode	Bp	Bi	Cp	Ci	Dp	Di	Mp	Mi
p_- (MPa)		5.95	3.39	6.04	4.26	6.42	4.57	5.95	5.95
I_{spta} (mW/cm^2)		67	274	90	312	342	632	290	290
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	1.0	2.0	1.0	1.0	1.0	1.0	1.0	1.0
	Frequency (MHz)	7.27	7.27	8.89	7.27	8.89	6.15	7.27	7.27
I_p (mm)		7	10	7	7	8	8	9	9
W_{pb6} (II) (mm)		0.8	3.0	0.9	0.9	0.7	0.7	0.5	0.5
(⊥) (mm)		0.9	1.0	0.9	1.0	0.9	1.0	0.9	0.9
prr (kHz)						0.6	1.6	1.0	1.0
srr (Hz)		22.8	72.3	6.1	40.2				
Output beam dimensions (II) (mm)		5.3	10.8	2.4	2.4	3.4	3.4	5.3	5.3
(⊥) (mm)		2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
f_{awf} (MHz)		7.4	7.2	8.6	7.3	8.6	6.3	7.4	7.4
APF [c] (%)		68	120	67	96	63	89	68	68
AIF [d] (%)		68	120	67	96	63	89	68	68
Maximum power (mW)		78	93	18	43	10	6	7	7
I_{ob} (mW/cm^2)		588	345	302	712	113	75	53	53
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Acoustic output information for the SONOLINE Antares ultrasound imaging system. Type: **VFX13-5**

Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division

Parameter	**Mode**	**Bp**	**Bi**	**Cp**	**Ci**	**Dp**	**Di**	**Mp**	**Mi**
p_{-} (MPa)		6.31	3.05	5.73	2.31	6.69	5.29	6.31	6.02
I_{spta} (mW/cm^2)		34	253	35	520	97	925	306	348
System settings:	Power (%)	100	100	100	100	100	100	100	100
	Focus (cm)	1.0	3.0	1.2	6.0	1.0	1.5	1.0	1.0
	Frequency (MHz)	8.00	7.27	7.27	6.15	8.89	6.15	8.00	7.27
I_p (mm)		14	13	9	12	9	12	11	10
W_{pb6} (II) (mm)		1.1	4.1	0.8	9.5	0.5	0.9	0.4	0.5
(⊥) (mm)		1.2	1.0	1.2	1.1	1.1	1.2	1.0	1.1
prr (kHz)						0.1	1.6	1.0	1.0
srr (Hz)		18.1	68.9	5.6	13.6				
Output beam dimensions (II) (mm)		5.3	16.1	3.0	14.3	3.4	5.0	5.3	5.3
(⊥) (mm)		3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
f_{awf} (MHz)		8.0	6.9	7.3	6.3	8.8	6.3	8.0	7.5
APF [c] (%)		70	144	77	190	66	83	70	73
AIF [d] (%)		70	144	77	190	66	83	70	73
Maximum power (mW)		64	77	8	62	2	14	7	7
I_{ob} (mW/cm^2)		398	160	89	146	22	91	45	44
Power-up mode		B	B	B	B	B	B	B	B
Initialization mode		B	B	B	B	B	B	B	B
Acoustic output freeze		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)		n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
I_{ts} (mm)		Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		-	-	-	-	B+D	B+D	B+M	B+M
						B+C+D	B+C+D	B+C+M	B+C+M

a Acoustic power-up fraction
b Acoustic initialization fraction

Acoustic output information is presented according to the recommendations of the International Electrotechnical Commission (IEC) as expressed in IEC 61157.

Track 3, FDA 510(k) Acoustic Output Reporting

Data presented in Track 3 format represents the average MI/TI values for five transducers measured under worst-case acoustic output conditions. The on-screen MI/TI values are based on measurements on one transducer under worst case acoustic output conditions - rounded up to the nearest display increment. It is possible that the values displayed on screen may exceed the MI/TI values presented in the Track 3 format.

Summary Table for Acoustic Output

A "yes" indicates that either MI or TI index is greater than 1.0 for each transducer/mode combination. A Track 3 acoustic output table is supplied for each transducer/mode combination marked with "yes."

The asterisk in the Power column indicates that no data is provided because it is the same as its corresponding Color flow data.

	Operating Mode					
Transducer Model	**B-mode (2D)**	**2D-THI**	**Color Flow**	**Power**	**M-mode**	**Pulsed Doppler**
C5-2	yes	yes	yes	*	yes	yes
CX5-2	yes	yes	yes	*	yes	yes
CH6-2	yes	yes	yes	*	yes	yes
EC9-4	yes	yes				yes
P10-4	yes	yes	yes	*		yes
PH4-1	yes	yes	yes	*	yes	yes
VF7-3	yes	yes	yes	*	yes	yes
VFX9-4	yes	yes	yes	*	yes	yes
VF10-5	yes	yes	yes	*	yes	yes
VF13-5	yes	yes	yes	*	yes	yes
VFX13-5	yes	yes	yes	*	yes	yes

The following rules apply to the summary table:

B-mode (2D)	No other mode active. Only MI (when larger than 1.0) is reported for this mode.
M-mode	Includes simultaneous B-mode.
PW-Doppler	In duplex modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Color Flow or Power	Includes simultaneous color flow M-mode, B-mode, and Doppler. In combined modes, the largest displayed TIS (scanned or non-scanned) is reported if it is larger than 1.0.
Other	The output is reported as a separate mode if the largest formulation of TIS, TIB, or TIC (if an intended use) is greater than the corresponding value reported for all constituent mode. TIC is reported if the transducer is intended for transcranial or neonatal cephalic use.

Definitions

Symbol	Definition	Units
MI	Mechanical Index	N/A
TIS Scan	Soft Tissue Thermal Index in autoscanning mode	N/A
TIS Non-scan	Soft Tissue Thermal Index in non-autoscanning mode	N/A
TIB	Bone Thermal Index	N/A
TIC	Cranial Thermal Index	N/A
A_{aprt}	Area of the active aperture	cm^2
$P_{r.3}$	Derated peak rarefactional pressure	MPa
W_o	Ultrasonic power, except for TIS Scan, in which case it is the ultrasonic power passing through a one centimeter window.	mW
$W_{.3}(Z_1)$	Derated ultrasonic power at axial distance Z_1	mW
$I_{TA.3}(Z_1)$	Derated spatial-peak, temporal-average intensity at axial distance Z_1	mW/cm^2
Z_1	Axial distance corresponding to the location of the max $[W_{.3}(Z_1), I_{TA.3}(Z) \times 1\ cm^2)]$, where $Z > Z_{bp}$.	cm^2
Z_{bp}	$1.69\ (A_{aprt})^{1/2}$	cm
Z_{sp}	For MI: axial distance at which $P_{r.3}$ is measured For TIB: axial distance at which TIB is a maximum (i.e., $Z_{sp} = Z_{B.3}$)	cm
$d_{eq}\ (Z_{sp})$	Equivalent beam diameter as a function of axial distance, and is equal to where ITA (Z) is the temporal-average intensity as a function of Z	cm
f_c	Center frequency	MHz
Dim. of A_{aprt}	Active aperture dimensions for the azimuth and elevational planes	cm
PD	Pulse duration	µs
PRF	Pulse repetition frequency	Hz
Pr @ PII max	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum	MPa
d_{eq}@ PII max	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum	cm
FL	Focal Length, or azimuthal and elevational lengths, if different	cm
$I_{pa.3}$ @ MI max	Derated pulse-average intensity at the point of global maximum	W/cm^2

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C5-2** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	1.50	(a)	-	-	-	(a)
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	2.48					
	W_o	(mW)		#	-		-	#
	min of [$W_{.3}(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.60				-	
	d_{eq} (Z_{sp})	(cm)					-	
	f_c	(MHz)	2.74	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.87					
	PRF	(Hz)	8.19					
	Pr @ PII max	(MPa)	2.89					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	253.33					
Operator Control	Focus (mm)		2.00	#	-	-	-	#
	Frequency (MHz)		2.50	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C5-2** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	1.45	(a)	-	-	-	(a)
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	2.43					
	W_o	(mW)		#	-		-	#
	min of [$W_{.3}(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.60				-	
	d_{eq} (Z_{sp})	(cm)					-	
	f_c	(MHz)	2.77	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.45					
	PRF	(Hz)	5.34					
	Pr @ PII max	(MPa)	2.83					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	187.98					
Operator Control	Focus (mm)		2.00	#	-	-	-	#
	Frequency (MHz)		2.50	#	-	-	-	#
	Res/Speed		3	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C5-2** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	(a)	0.94	-	-	-	2.55
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	#					
	W_o	(mW)		52.36	-		-	113.78
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				-	
	$d_{eq}(Z_{sp})$	(cm)					-	
	f_c	(MHz)	#	3.53	-	-	-	2.59
	Dim. of A_{aprt}	X (cm)		1.65	-	-	-	5.35
		Y (cm)		1.12	-	-	-	1.12
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		6.95	-	-		28.00
		FLy (cm)		5.00	-	-		5.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	6.95	-	-	-	28.00
	Res/Speed		#	5	-	-	-	0
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	3.64	-	-	-	2.50

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C5-2** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.62	2.31	2.20
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		85.44	243.24
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				50.38		
	Z1	(cm)				4.60		
	Zbp	(cm)				4.14		
	Zsp	(cm)	#				4.50	
	deq (Zsp)	(cm)					0.37	
	fc	(MHz)	#	-	-	2.59	2.60	2.59
	Dim. of Aaprt	X (cm)		-	-	5.35	1.42	5.35
		Y (cm)		-	-	1.12	1.12	1.12
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.35	
	Focal Length	FLx (cm)		-	-	27.49		27.44
		FLy (cm)		-	-	5.00		5.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	2.50	2.50	2.50
	Focus (mm)		#	-	-	27.49	5.98	27.44
	Gate Size (cm)		#	-	-	0.10	0.20	0.20
	Sample Rate (Hz)		#	-	-	17361	28409	17361

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **C5-2** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.76	1.42	1.38
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		80.60	114.51
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				54.01		
	Z1	(cm)				3.60		
	Zbp	(cm)				3.07		
	Zsp	(cm)	#				4.30	
	deq (Zsp)	(cm)					0.59	
	fc	(MHz)	#	-	-	2.95	2.61	3.07
	Dim. of Aaprt	X (cm)		-	-	2.95	2.17	3.02
		Y (cm)		-	-	1.12	1.12	1.12
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					16.23	
	Focal Length	FLx (cm)		-	-	8.00		10.00
		FLy (cm)		-	-	5.00		5.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	3.08	2.50	3.08
	Focus (mm)		#	-	-	8.00	6.00	10.00
	Gate Size (cm)		#	-	-	1.00	1.00	1.00
	Sample Rate (Hz)		#	-	-	600	600	600

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CX5-2** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.47	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.41					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	4.00				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	2.71	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.68					
	PRF	(Hz)	35.77					
	Pr @ PII max	(MPa)	3.37					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	384.41					
Operator Control	Focus (mm)		4.00	#	-	-	-	#
	Frequency (MHz)		2.50	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CX5-2** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.07	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	1.55					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	6.40				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	2.09	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.97					
	PRF	(Hz)	4.08					
	Pr @ PII max	(MPa)	2.43					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	144.29					
Operator Control	Focus (mm)		6.00	#	-	-	-	#
	Frequency (MHz)		1.82	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CX5-2** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	1.15	-	-	-	2.31
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		104.91	-		-	221.60
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	3.57	-	-	-	2.68
	Dim. of Aaprt	X (cm)		1.91	-	-	-	3.89
		Y (cm)		1.60	-	-	-	1.60
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		8.05	-	-		16.03
		FLy (cm)		4.00	-	-		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	8.05	-	-	-	16.03
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	3.64	-	-	-	2.67

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CX5-2** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.81	2.81	2.44
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		137.87	295.19
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				61.46		
	Z1	(cm)				4.90		
	Zbp	(cm)				2.93		
	Zsp	(cm)	#				6.60	
	deq (Zsp)	(cm)					0.37	
	fc	(MHz)	#	-	-	2.75	2.41	2.68
	Dim. of Aaprt	X (cm)		-	-	1.88	1.88	4.49
		Y (cm)		-	-	1.60	1.60	1.60
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.35	
	Focal Length	FLx (cm)		-	-	8.02		20.04
		FLy (cm)		-	-	4.00		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	2.67	2.22	2.67
	Focus (mm)		#	-	-	8.02	8.02	20.04
	Gate Size (cm)		#	-	-	0.10	0.10	0.10
	Sample Rate (Hz)		#	-	-	31250	31250	24083

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CX5-2** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.52	0.96	1.47
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		67.22	144.53
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				36.16		
	Z1	(cm)				3.30		
	Zbp	(cm)				2.75		
	Zsp	(cm)	#				3.40	
	deq (Zsp)	(cm)					0.85	
	fc	(MHz)	#	-	-	3.02	2.65	3.05
	Dim. of Aaprt	X (cm)		-	-	2.95	2.93	2.95
		Y (cm)		-	-	0.90	0.90	1.60
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					21.48	
	Focal Length	FLx (cm)		-	-	10.00		16.00
		FLy (cm)		-	-	4.00		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	3.08	2.50	3.08
	Focus (mm)		#	-	-	10.00	8.00	16.00
	Gate Size (cm)		#	-	-	1.00	1.00	1.00
	Sample Rate (Hz)		#	-	-	600	600	600

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH6-2** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	1.54	(a)	-	-	-	(a)
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	2.87					
	W_o	(mW)		#	-		-	#
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	4.10				-	
	d_{eq} (Z_{sp})	(cm)					-	
	f_c	(MHz)	3.46	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.63					
	PRF	(Hz)	27.66					
	Pr @ PII max	(MPa)	4.68					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	282.78					
Operator Control	Focus (mm)		4.00	#	-	-	-	#
	Frequency (MHz)		3.64	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH6-2** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	1.52	(a)	-	-	-	(a)
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	2.41					
	W_o	(mW)		#	-		-	#
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	4.20				-	
	d_{eq} (Z_{sp})	(cm)					-	
	f_c	(MHz)	2.53	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.75					
	PRF	(Hz)	15.53					
	Pr @ PII max	(MPa)	3.48					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	276.93					
Operator Control	Focus (mm)		4.00	#	-	-	-	#
	Frequency (MHz)		2.22	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH6-2** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	(a)	1.73	-	-	-	3.36
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	#					
	W_o	(mW)		175.95	-		-	362.94
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				-	
	$d_{eq}(Z_{sp})$	(cm)					-	
	f_c	(MHz)	#	3.11	-	-	-	3.09
	Dim. of A_{aprt}	X (cm)		1.44	-	-	-	3.99
		Y (cm)		1.20	-	-	-	1.20
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		6.09	-	-		16.50
		FLy (cm)		6.90	-	-		6.90
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	6.09	-	-	-	16.50
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	3.08	-	-	-	3.08

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH6-2** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	1.59	3.85	3.81
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		175.04	392.58
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				107.95		
	Z1	(cm)				2.80		
	Zbp	(cm)				2.39		
	Zsp	(cm)	#				4.60	
	deq (Zsp)	(cm)					0.38	
	fc	(MHz)	#	-	-	3.09	3.11	3.09
	Dim. of Aaprt	X (cm)		-	-	1.66	1.44	4.33
		Y (cm)		-	-	1.20	1.20	1.20
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.37	
	Focal Length	FLx (cm)		-	-	6.96		17.85
		FLy (cm)		-	-	6.90		6.90
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	3.08	3.08	3.08
	Focus (mm)		#	-	-	6.96	6.02	17.85
	Gate Size (cm)		#	-	-	0.20	0.20	0.20
	Sample Rate (Hz)		#	-	-	1562	1953	976

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **CH6-2** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.89	1.33	2.06
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		133.73	166.09
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				58.42		
	Z1	(cm)				2.60		
	Zbp	(cm)				2.57		
	Zsp	(cm)	#				2.60	
	deq (Zsp)	(cm)					1.28	
	fc	(MHz)	#	-	-	3.21	3.21	3.41
	Dim. of Aaprt	X (cm)		-	-	1.93	1.93	2.67
		Y (cm)		-	-	1.20	1.20	1.20
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					22.67	
	Focal Length	FLx (cm)		-	-	6.00		14.00
		FLy (cm)		-	-	6.90		6.90
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	-	3.64	3.64	3.64
	Focus (mm)		#	-	-	6.00	6.00	14.00
	Gate Size (cm)		#	-	-	1.00	1.00	1.00
	Sample Rate (Hz)		#	-	-	600	600	600

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.25	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.50					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.80				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	4.03	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.59					
	PRF	(Hz)	30.06					
	Pr @ PII max	(MPa)	3.10					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	340.15					
Operator Control	Focus (mm)		1.50	#	-	-	-	#
	Frequency (MHz)		3.64	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.50	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.01					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.70				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	4.13	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.32					
	PRF	(Hz)	13.20					
	Pr @ PII max	(MPa)	3.71					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	399.12					
Operator Control	Focus (mm)		1.50	#	-	-	-	#
	Frequency (MHz)		3.64	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **EC9-4** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	1.08	-	1.73	1.24
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	45.96		31.77	45.96
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				2.10	
	deq (Zsp)	(cm)					0.20	
	fc	(MHz)	#	-	4.96	-	5.06	4.96
	Dim. of Aaprt	X (cm)		-	1.12	-	0.61	1.12
		Y (cm)		-	0.60	-	0.60	0.60
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.20	
	Focal Length	FLx (cm)		-	10.01	-		10.01
		FLy (cm)		-	3.00	-		3.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	5.00	-	5.00	5.00
	Focus (mm)		#	-	10.01	-	2.52	10.01
	Gate Size (cm)		#	-	0.10	-	0.10	0.10
	Sample Rate (Hz)		#	-	24083	-	34722	24083

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P10-4** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.24	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.72					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	0.70				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	4.78	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.45					
	PRF	(Hz)	44.90					
	Pr @ PII max	(MPa)	3.06					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	237.91					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		4.44	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P10-4** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	1.49	(a)	-	-	-	(a)
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	3.22					
	W_o	(mW)		#	-		-	#
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.90				-	
	d_{eq} (Z_{sp})	(cm)					-	
	f_c	(MHz)	4.65	#	-	-	-	#
	Dim. of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.26					
	PRF	(Hz)	16.76					
	Pr @ PII max	(MPa)	4.13					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	350.94					
Operator Control	Focus (mm)		2.00	#	-	-	-	#
	Frequency (MHz)		5.33	#	-	-	-	#
	Res/Speed		2	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P10-4** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Maximum Value		---	(a)	1.43	-	-	-	1.90
Associated Acoustic Parameters	$P_{r.3}$	(MPa)	#					
	W_o	(mW)		54.82	-		-	68.14
	min of [$W_3(Z_1)$, $I_{TA.3}(Z_1)$]	(mW)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				-	
	$d_{eq}(Z_{sp})$	(cm)					-	
	f_c	(MHz)	#	5.54	-	-	-	5.23
	Dim. of A_{aprt}	X (cm)		1.00	-	-	-	1.32
		Y (cm)		0.50	-	-	-	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		4.00	-	-		7.02
		FLy (cm)		3.00	-	-		3.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	4.00	-	-	-	7.02
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	5.71	-	-	-	5.00

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **P10-4** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	1.93	-	1.54	2.09
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	69.61		72.83	76.54
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				2.10	
	deq (Zsp)	(cm)					0.50	
	fc	(MHz)	#	-	5.83	-	5.23	4.50
	Dim. of Aaprt	X (cm)		-	1.32	-	1.32	1.32
		Y (cm)		-	0.50	-	0.50	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.31	
	Focal Length	FLx (cm)		-	7.00	-		7.00
		FLy (cm)		-	3.00	-		3.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Frequency (MHz)		#	-	5.71	-	5.00	4.44
	Focus (mm)		#	-	7.00	-	7.00	7.00
	Gate Size (cm)		#	-	0.10	-	0.10	0.15
	Sample Rate (Hz)		#	-	17361	-	17361	14204

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **PH4-1** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.43	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.19					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	4.10				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	2.33	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.84					
	PRF	(Hz)	7.63					
	Pr @ PII max	(MPa)	2.96					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	259.70					
Operator Control	Focus (mm)		4.00	#	-	-	-	#
	Frequency (MHz)		2.22	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **PH4-1** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.39	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.08					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	4.20				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	2.27	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.50					
	PRF	(Hz)	3.81					
	Pr @ PII max	(MPa)	2.77					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	285.19					
Operator Control	Focus (mm)		4.00	#	-	-	-	#
	Frequency (MHz)		2.22	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **PH4-1** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	1.28	-	-	-	3.40
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		115.64	-		-	238.84
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	2.05	-	-	-	2.05
	Dim. of Aaprt	X (cm)		1.01	-	-	-	2.82
		Y (cm)		1.35	-	-	-	1.35
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		4.02	-	-		23.45
		FLy (cm)		7.00	-	-		7.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	4.02	-	-	-	23.45
	Res/Speed		#	4	-	-	-	4
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	2.67	-	-	-	2.00

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **PH4-1** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	1.30	3.87	3.67
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		165.91	323.12
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				127.68		
	Z1	(cm)				6.30		
	Zbp	(cm)				3.30		
	Zsp	(cm)	#				4.00	
	deq (Zsp)	(cm)					0.54	
	fc	(MHz)	#	-	-	2.14	2.12	2.14
	Dim. of Aaprt	X (cm)		-	-	2.82	1.06	2.82
		Y (cm)		-	-	1.35	1.35	1.35
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.51	
	Focal Length	FLx (cm)		-	-	20.07		20.07
		FLy (cm)		-	-	7.00		7.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	-	2.00	2.00	2.00
	Res/Speed		#	-	-	20.07	4.21	20.07
	Ensemble Size		#	-	-	0.10	0.10	0.10
	Frequency (MHz)		#	-	-	31250	26042	31250

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **PH4-1** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.99	1.74	2.02
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		150.47	150.47
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				81.86		
	Z1	(cm)				2.80		
	Zbp	(cm)				2.79		
	Zsp	(cm)	#				2.80	
	deq (Zsp)	(cm)					1.20	
	fc	(MHz)	#	-	-	2.53	2.53	2.53
	Dim. of Aaprt	X (cm)		-	-	2.01	2.01	2.01
		Y (cm)		-	-	1.35	1.35	1.35
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					31.52	
	Focal Length	FLx (cm)		-	-	10.01		10.01
		FLy (cm)		-	-	7.00		7.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	-	2.67	2.67	2.67
	Res/Speed		#	-	-	10.01	10.01	10.01
	Ensemble Size		#	-	-	1.00	1.00	1.00
	Frequency (MHz)		#	-	-	600	600	600

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF7-3** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.51	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.89					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	2.60				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	3.54	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.68					
	PRF	(Hz)	14.76					
	Pr @ PII max	(MPa)	3.83					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	404.10					
Operator Control	Focus (mm)		3.00	#	-	-	-	#
	Frequency (MHz)		3.33	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF7-3** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.49	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.92					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	2.00				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	3.79	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.51					
	PRF	(Hz)	16.14					
	Pr @ PII max	(MPa)	3.58					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	431.67					
Operator Control	Focus (mm)		2.00	#	-	-	-	#
	Frequency (MHz)		3.33	#	-	-	-	#
	Res/Speed		3	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF7-3** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	0.94	-	-	-	2.11
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		82.13	-		-	161.80
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	4.15	-	-	-	3.38
	Dim. of Aaprt	X (cm)		1.66	-	-	-	3.82
		Y (cm)		0.75	-	-	-	0.75
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		7.00	-	-		16.00
		FLy (cm)		4.00	-	-		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	7.00	-	-	-	16.00
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	12	-	-	-	12
	Frequency (MHz)		#	4.21	-	-	-	3.33

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF7-3** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	1.42	4.20	2.19
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		87.11	169.15
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				81.25		
	Z1	(cm)				2.90		
	Zbp	(cm)				2.89		
	Zsp	(cm)	#				3.70	
	deq (Zsp)	(cm)					0.18	
	fc	(MHz)	#	-	-	3.66	3.78	3.66
	Dim. of Aaprt	X (cm)		-	-	3.90	1.58	3.90
		Y (cm)		-	-	0.75	0.75	0.75
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.18	
	Focal Length	FLx (cm)		-	-	10.00		10.00
		FLy (cm)		-	-	4.00		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	-	3.33	3.33	3.33
	Res/Speed		#	-	-	10.00	3.98	10.00
	Ensemble Size		#	-	-	0.10	0.10	0.10
	Frequency (MHz)		#	-	-	26042	26042	26042

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF7-3** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.69	1.49	1.15
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		74.56	74.99
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				40.06		
	Z1	(cm)				2.50		
	Zbp	(cm)				2.44		
	Zsp	(cm)	#				2.50	
	deq (Zsp)	(cm)					0.61	
	fc	(MHz)	#	-	-	3.60	3.60	3.53
	Dim. of Aaprt	X (cm)		-	-	2.79	2.79	2.79
		Y (cm)		-	-	0.75	0.75	0.75
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					19.07	
	Focal Length	FLx (cm)		-	-	9.00		12.00
		FLy (cm)		-	-	4.00		4.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	-	3.33	3.33	3.33
	Res/Speed		#	-	-	9.00	9.00	12.00
	Ensemble Size		#	-	-	1.00	1.00	1.00
	Frequency (MHz)		#	-	-	600	600	600

a **This Index is not relevant to this operating mode.**
b **This transducer is not intended for transcranial or neonatal cephalic uses.**
c **This formulation for TIS is less than that for an alternate formulation in this mode.**
**No data is provided for this operation condition since the maximum index value is not reported for the reason listed.**

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX9-4** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.51	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.13					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.50				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	4.28	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.46					
	PRF	(Hz)	17.81					
	Pr @ PII max	(MPa)	3.85					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	455.54					
Operator Control	Focus (mm)		3.00	#	-	-	-	#
	Frequency (MHz)		4.00	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX9-4** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.25	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	2.67					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.10				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	4.79	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.17					
	PRF	(Hz)	6.45					
	Pr @ PII max	(MPa)	3.04					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	621.09					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		4.21	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX9-4** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	2.03	-	-	-	2.32
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		99.38	-		-	193.29
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	4.98	-	-	-	4.98
	Dim. of Aaprt	X (cm)		0.48	-	-	-	3.28
		Y (cm)		0.90	-	-	-	0.90
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		2.01	-	-		13.75
		FLy (cm)		2.00	-	-		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	2.01	-	-	-	13.75
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	14	-	-	-	14
	Frequency (MHz)		#	5.00	-	-	-	5.00

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX9-4** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	2.50	-	2.76	2.51
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	79.78		134.05	185.90
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				3.40	
	deq (Zsp)	(cm)					0.41	
	fc	(MHz)	#	-	6.59	-	4.20	4.98
	Dim. of Aaprt	X (cm)		-	1.00	-	2.15	2.99
		Y (cm)		-	0.90	-	0.90	0.90
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.23	
	Focal Length	FLx (cm)		-	3.02	-		9.01
		FLy (cm)		-	2.00	-		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	6.67	-	4.00	5.00
	Res/Speed		#	-	3.02	-	6.43	9.01
	Ensemble Size		#	-	0.10	-	0.10	0.10
	Frequency (MHz)		#	-	7102	-	13020	4340

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX9-4** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	-	0.66	1.23	1.17
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	-		48.95	83.56
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				30.77		
	Z1	(cm)				3.20		
	Zbp	(cm)				2.66		
	Zsp	(cm)	#				3.70	
	deq (Zsp)	(cm)					0.32	
	fc	(MHz)	#	-	-	4.52	4.10	4.52
	Dim. of Aaprt	X (cm)		-	-	2.76	1.44	2.76
		Y (cm)		-	-	0.90	0.90	0.90
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					9.51	
	Focal Length	FLx (cm)		-	-	9.00		9.00
		FLy (cm)		-	-	2.00		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	-	5.00	4.00	5.00
	Res/Speed		#	-	-	9.00	4.00	9.00
	Ensemble Size		#	-	-	1.00	1.00	1.00
	Frequency (MHz)		#	-	-	960	960	960

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.48	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.69					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.40				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	6.20	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.40					
	PRF	(Hz)	48.34					
	Pr @ PII max	(MPa)	4.98					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	625.82					
Operator Control	Focus (mm)		1.50	#	-	-	-	#
	Frequency (MHz)		5.71	#	-	-	-	#
	Res/Speed		0	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.62	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.80					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.60				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	5.49	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.25					
	PRF	(Hz)	8.43					
	Pr @ PII max	(MPa)	5.05					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	569.14					
Operator Control	Focus (mm)		2.00	#	-	-	-	#
	Frequency (MHz)		5.00	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	1.96	-	-	-	2.05
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		87.93	-		-	89.81
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	7.11	-	-	-	7.11
	Dim. of Aaprt	X (cm)		1.38	-	-	-	2.32
		Y (cm)		0.50	-	-	-	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		5.81	-	-		9.75
		FLy (cm)		2.00	-	-		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	5.81	-	-	-	9.75
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	14	-	-	-	14
	Frequency (MHz)		#	7.27	-	-	-	7.27

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	4.26	-	2.77	3.43
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	121.92		60.48	166.85
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				1.30	
	deq (Zsp)	(cm)					0.32	
	fc	(MHz)	#	-	7.34	-	4.79	5.80
	Dim. of Aaprt	X (cm)		-	1.96	-	0.96	2.32
		Y (cm)		-	0.50	-	0.50	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.24	
	Focal Length	FLx (cm)		-	8.27	-		9.78
		FLy (cm)		-	2.00	-		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	7.27	-	4.71	5.71
	Res/Speed		#	-	8.27	-	4.02	9.78
	Ensemble Size		#	-	0.20	-	0.20	0.20
	Frequency (MHz)		#	-	39062	-	5580	26042

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF10-5** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	2.42	-	1.64	1.96
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	83.75		72.98	83.75
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				1.50	
	deq (Zsp)	(cm)					0.53	
	fc	(MHz)	#	-	6.07	-	6.09	6.07
	Dim. of Aaprt	X (cm)		-	1.79	-	1.43	1.79
		Y (cm)		-	0.50	-	0.50	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					15.92	
	Focal Length	FLx (cm)		-	5.00	-		5.00
		FLy (cm)		-	2.00	-		2.00
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	5.71	-	5.71	5.71
	Res/Speed		#	-	5.00	-	4.00	5.00
	Ensemble Size		#	-	1.00	-	1.00	1.00
	Frequency (MHz)		#	-	960	-	960	960

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.57	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	4.33					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	0.80				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	7.40	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.29					
	PRF	(Hz)	20.51					
	Pr @ PII max	(MPa)	5.16					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	679.99					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		7.27	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.50	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.87					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	0.90				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	6.61	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.20					
	PRF	(Hz)	21.09					
	Pr @ PII max	(MPa)	4.49					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	561.19					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		6.15	#	-	-	-	#
	Res/Speed		3	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	2.29	-	-	-	2.82
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		33.61	-		-	34.06
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	7.26	-	-	-	7.26
	Dim. of Aaprt	X (cm)		0.36	-	-	-	0.36
		Y (cm)		0.25	-	-	-	0.25
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		1.50	-	-		1.50
		FLy (cm)		0.75	-	-		0.75
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	1.50	-	-	-	1.50
	Res/Speed		#	0	-	-	-	0
	Ensemble Size		#	14	-	-	-	14
	Frequency (MHz)		#	7.27	-	-	-	7.27

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)

(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	3.35	-	3.08	3.47
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	109.45		62.96	109.45
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				0.80	
	deq (Zsp)	(cm)					0.32	
	fc	(MHz)	#	-	6.43	-	6.45	6.43
	Dim. of Aaprt	X (cm)		-	1.95	-	0.82	1.95
		Y (cm)		-	0.25	-	0.25	0.25
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.19	
	Focal Length	FLx (cm)		-	5.83	-		5.83
		FLy (cm)		-	0.75	-		0.75
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	6.15	-	6.15	6.15
	Res/Speed		#	-	5.83	-	2.50	5.83
	Ensemble Size		#	-	0.10	-	0.10	0.10
	Frequency (MHz)		#	-	31250	-	39062	31250

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VF13-5** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	2.00	-	1.00	1.85
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	61.28		30.64	61.28
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				1.00	
	deq (Zsp)	(cm)					0.42	
	fc	(MHz)	#	-	6.85	-	7.10	6.85
	Dim. of Aaprt	X (cm)		-	2.16	-	1.08	2.16
		Y (cm)		-	0.25	-	0.25	0.25
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					12.43	
	Focal Length	FLx (cm)		-	4.00	-		4.00
		FLy (cm)		-	0.75	-		0.75
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	7.27	-	7.27	7.27
	Res/Speed		#	-	4.00	-	2.00	4.00
	Ensemble Size		#	-	0.50	-	0.50	0.50
	Frequency (MHz)		#	-	960	-	960	960

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX13-5** Operating mode: **2D-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.52	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	4.17					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.00				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	7.55	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.27					
	PRF	(Hz)	18.09					
	Pr @ PII max	(MPa)	5.41					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	797.84					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		7.27	#	-	-	-	#
	Res/Speed		5	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX13-5** Operating mode: **2D-THI**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	1.35	(a)	-	-	-	(a)
Associated Acoustic Parameters	Pr.3	(MPa)	3.64					
	Wo	(mW)		#	-		-	#
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	0.90				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	7.39	#	-	-	-	#
	Dim. of Aaprt	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.19					
	PRF	(Hz)	14.73					
	Pr @ PII max	(MPa)	4.20					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		#	-	-		#
		FLy (cm)		#	-	-		#
	I pa.3 @ MI max	(W/cm2)	723.21					
Operator Control	Focus (mm)		1.00	#	-	-	-	#
	Frequency (MHz)		6.15	#	-	-	-	#
	Res/Speed		3	#	-	-	-	#

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX13-5** Operating mode: **Color / Power**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	1.48	-	-	-	2.33
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		36.97	-		-	29.76
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				-	
	deq (Zsp)	(cm)					-	
	fc	(MHz)	#	8.69	-	-	-	7.30
	Dim. of Aaprt	X (cm)		0.30	-	-	-	0.30
		Y (cm)		0.30	-	-	-	0.30
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					-	
	Focal Length	FLx (cm)		1.30	-	-		1.30
		FLy (cm)		1.10	-	-		1.10
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	1.30	-	-	-	1.30
	Res/Speed		#	5	-	-	-	5
	Ensemble Size		#	14	-	-	-	14
	Frequency (MHz)		#	8.89	-	-	-	7.27

a This Index is not relevant to this operating mode.
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c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX13-5** Operating mode: **Pulsed Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	2.79	-	1.76	1.95
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	65.82		29.52	67.21
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				1.10	
	deq (Zsp)	(cm)					0.19	
	fc	(MHz)	#	-	8.91	-	8.83	7.36
	Dim. of Aaprt	X (cm)		-	1.95	-	0.64	1.95
		Y (cm)		-	0.30	-	0.30	0.30
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					0.16	
	Focal Length	FLx (cm)		-	5.84	-		5.84
		FLy (cm)		-	1.10	-		1.10
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	8.89	-	8.89	7.27
	Res/Speed		#	-	5.84	-	1.92	5.84
	Ensemble Size		#	-	0.10	-	0.10	0.10
	Frequency (MHz)		#	-	14204	-	4882	1775

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table - Track 3, FDA 510(k)
(Per transducer/mode that exceeds MI or TI value of 1.0)

Transducer model: **VFX13-5** Operating mode: **M-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1	Aaprt >1		
Maximum Value		---	(a)	-	1.61	-	0.98	1.51
Associated Acoustic Parameters	Pr.3	(MPa)	#					
	Wo	(mW)		-	54.67		27.33	54.67
	min of [W.3(Z1), ITA.3(Z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	#				1.00	
	deq (Zsp)	(cm)					0.39	
	fc	(MHz)	#	-	6.19	-	6.76	6.19
	Dim. of Aaprt	X (cm)		-	2.16	-	1.08	2.16
		Y (cm)		-	0.30	-	0.30	0.30
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	Pr @ PII max	(MPa)	#					
	d eq@ PII max	(cm)					10.79	
	Focal Length	FLx (cm)		-	4.00	-		4.00
		FLy (cm)		-	1.10	-		1.10
	I pa.3 @ MI max	(W/cm2)	#					
Operator Control	Focus (mm)		#	-	7.27	-	7.27	7.27
	Res/Speed		#	-	4.00	-	2.00	4.00
	Ensemble Size		#	-	0.50	-	0.50	0.50
	Frequency (MHz)		#	-	960	-	960	960

a This Index is not relevant to this operating mode.
b This transducer is not intended for transcranial or neonatal cephalic uses.
c This formulation for TIS is less than that for an alternate formulation in this mode.
No data is provided for this operation condition since the maximum index value is not reported for the reason listed.

2 Transducer Accessories

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Transducer Accessories

Attachment procedures for the following accessories are presented in this chapter. Accessories for each transducer are listed in the following table.

Instructions for Use

Cleaning and Care Ch 2

Accessory	Curved Array	Linear Array	Phased Array	Endocavity
Transducer Sheath	C5-2 CX5-2 CH6-2	VF7-3 VFX9-4 VF10-5 VF13-5 VFX13-5	PH4-1	EC9-4
Gel Pad	C5-2 CX5-2 CH6-2	VF7-3 VFX9-4 VF10-5 VF13-5 VFX13-5	PH4-1	EC9-4
Needle Guide Bracket Kits, SG-1	C5-2 CX5-2			
Needle Guide Bracket Kits, SG-2			PH4-1	
Needle Guide Bracket Kits, SG-3		VF7-3 VFX9-4 VF10-5		
Needle Guide Bracket Kits, SG-4		VF13-5 VFX13-5		
Needle Guide Bracket Kits, SG-5	CH6-2			
Needle Guide Bracket Kits, Models EC-1 and EC9-4 (Disposable Endocavity Needle Guide)				EC9-4

Transducer Sheaths

Siemens makes every effort to manufacture safe and effective transducers. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endocavity or intraoperative scanning; during biopsy or puncture procedures; or when scanning patients with open wounds.

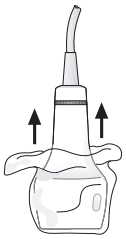
General Information ▪ Sheaths

⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and to be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ **WARNING:** Only a sterile transducer sheath provides the sterile barrier required for surgical or puncture procedures. To ensure sterility of a procedure, always place a sterile sheath on a transducer as transducers cannot be sterilized using hot steam, cold gas, or Ethylene Oxide (EOG) methods.

Transducer sheaths are single-use items used to ensure proper acoustic coupling and provide a prophylactic barrier for the intended ultrasound application. Sheaths are available for all transducers. Siemens recommends the use of market-cleared transducer sheaths.

Application ▪ Sheaths



Step-by-step instructions are provided for both non-sterile and sterile procedures.

To place the transducer in a sheath for non-sterile use:

Before applying any coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with water.

1. Remove the packaging and unfold the transducer sheath.
2. Apply a water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
3. Hold the transducer by the cable relief and unroll the sheath onto the transducer.
4. Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
5. Secure the sheath to the transducer housing or cable relief with the adhesive tapes or elastic bands.

To place the transducer in a sheath for sterile use:

Before applying any sterile coupling agent (gel) to the sheath, remove any powder in the sheath by rinsing with sterile water.

1. Using sterile technique, remove the packaging and unfold the transducer sheath.
2. Taking care not to contaminate the sheath, apply a sterile water-based coupling agent (gel) to the inside of the sheath and onto the face of the transducer.
3. Using sterile technique, hold the transducer by the cable relief and unroll the sheath onto the transducer and cable.
4. Pull the transducer sheath tightly over the face of the transducer to remove wrinkles.
5. Secure the sheath to the transducer cable with the adhesive tapes or elastic bands.

⚠ **WARNING:** After placing the sheath over the transducer, visually inspect the sheath to ensure there are no defects. Do not use the sheath if it has any holes or tears.

Disposal ▪ Sheaths

While wearing protective gloves, remove the transducer sheath from the transducer and dispose of it according to medical regulations for biohazardous waste.

Gel Pad

The gel pad is a disposable bacteriostatic standoff. It is used when superficial imaging requires an appropriate standoff for utilizing the focal zone of the transducer. The gel pad provides a fixed distance between the transducer face and the body surface.

⚠ **WARNING:** Ultrasound energy is transmitted more efficiently through the gel pad than through tissue. When using a standoff device of any kind, for example a waterpath or gel pad, the actual mechanical and thermal indices, MI and/or TI, may be higher than indicated in the output display on the system.

Transducer Reference

Compatible Transducers 2-3

Instructions for Use

Cleaning and Care Ch 2

Preparation for use

Before use, examine the gel pad for any material flaws. Any product showing flaws should not be used.

Needle Guide Brackets

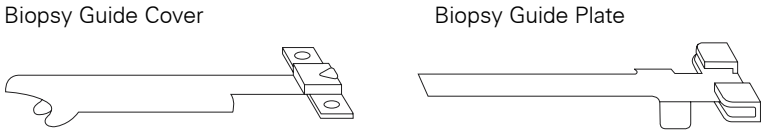
⚠ **WARNING:** Percutaneous procedures always involve heightened risk to the patient and to the operator handling biopsy needle guides. Clinicians using Siemens recommended biopsy devices under ultrasound guidance should be trained and must observe proper needle insertion sequencing with the needle guide in order to avoid undue discomfort and unnecessary risk and injury to the patient.

SG-1, SG-2, SG-3, SG-4, SG-5 Needle Guide Bracket Assemblies and EC9-4 Disposable Endocavity Needle Guide

Refer to the in-box instructions for attachment and care procedures.

EC-1 Needle Guide Bracket Kit

The EC-1 Needle Guide Bracket Kit consists of a biopsy guide cover, three biopsy guide plates (15G/16G, 17G/18G, 19G/20G/21G), an operation manual, and a carrying case. You can use the needle guide with needle sizes ranging from 14 to 22 gauge (2.11 mm to 0.64 mm). The biopsy bracket has a fixed angle.



Example of the EC-1 needle guide bracket assembly.

Preparation for Use ▪ EC-1 Needle Guide Bracket Kit

⚠ **WARNING:** Do not attempt to use the Needle Guide Bracket Kit until you have read the following instructions. The needle guide should only be used after proper training and after verifying the path of the needle.

⚠ **WARNING:** The needle guide is packaged non-sterile. Sterilize this product prior to its first use.

⚠ **WARNING:** Ensure that the needle guide is properly cleaned and sterilized before each use to avoid possible patient contamination.

⚠ **WARNING:** Before attaching the needle guide to the transducer, place the transducer in a sterile transducer sheath.

⚠ **WARNING:** There have been reports of severe allergic reactions to medical devices containing latex (natural rubber). Health care professionals are advised to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

⚠ **Caution:** Use only a water-based ultrasound coupling agent (gel) with this kit. Petroleum- or mineral oil-based materials can harm the transducer.

📖 **Transducer Reference**

Compatible Transducers 2-3

📖 **System Reference**

IMAGE: Needle Path Verification Ch 6

📖 **Instructions for Use**

Cleaning and Care Ch 2

To attach the needle guide to the transducer:

⚠ **WARNING:** Care must be taken to ensure that the needle guide is properly positioned. When properly positioned, the bracket will cover the colored ring on the transducer handle and the hook will be firmly against the transducer tip.

1. Place a sterile transducer sheath over the transducer.

   To ensure an accurate scan, there should not be any air bubbles or wrinkles between the transducer face and the transducer sheath.

📖 **Transducer Reference**

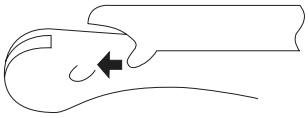
Transducer Sheaths 2-4

2. Select the correct biopsy guide plate.
3. Slide the biopsy guide plate into the biopsy guide cover until the plate locks.

📖 **System Reference**

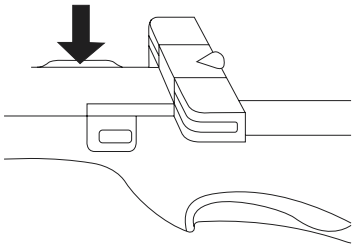
IMAGE:
Needle Path Verification Ch 6

4. Engage the biopsy adaptor fixing hook into the biopsy adaptor fixing slot at the tip of the transducer.



Example of fixing the biopsy bracket assembly to the transducer tip.

5. Insert the fixing hook at the other end into the fixing slot in the transducer grip section until it clicks.



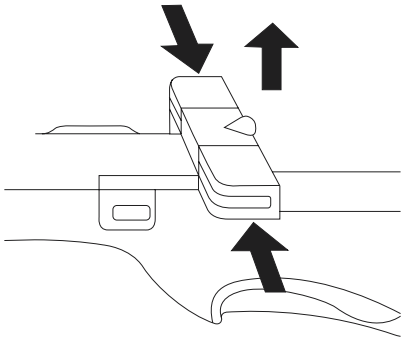
Example of fixing the biopsy bracket assembly to the transducer grip.

Note: For illustration purposes only, the transducer is shown without a transducer sheath. Always place a sterile transducer sheath over the transducer.

6. Before performing any patient procedure, verify the needle path.

Detachment

1. Hold the biopsy adapter firmly on the sides and pull it upwards to remove it from the transducer.



Example of Bracket disassembly.

2. Remove the biopsy guide plate from the biopsy guide cover.

Disposal

Dispose of the needle and the transducer sheath according to medical regulations for biohazardous waste.

If the biopsy bracket assembly becomes damaged or compromised in any way, dispose of it only after sterilizing. The assembly is made of polyetherimide resin. When disposing of the assembly, be sure to comply with all applicable laws or regulations.

3 Specialty Transducers

Reserved for future use.

Medical Ultrasound Safety

Part One: Bioeffects and Biophysics
Part Two: Prudent Use
Part Three: Implementing ALARA

American Institute of Ultrasound in Medicine

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Preface

With the availability of an output display in some present and in future diagnostic ultrasound equipment and the potential for higher output capabilities within these devices, it is incumbent upon the user to be knowledgeable of the uses of this equipment and the potential for ultrasound-induced bioeffects. The responsibility for patient safety is falling more heavily upon the ultrasound equipment user's shoulders and the need for an educational background in these uses and bioeffects is evident. In other words, there is a shift in responsibility for patient safety from the manufacturer to the user. In this regard, this tripartite brochure has been generated to provide the user with a working background and general principles that will provide for the understanding of the purpose and use of the Output Display Standard and how this display can be used to obtain diagnostic information with ultrasound exposure as low as reasonably achievable. The user education requirement represents a new level of responsibility that will permit increased ultrasound diagnostic capabilities within the context of user controlled ultrasound exposure. Information regarding ALARA and possible ultrasound bioeffects described in this brochure also applies to equipment without an output display.

—Michael S. Tenner, M.D.
AIUM President

Introduction

A new feature, called an output display, is becoming available on some recently introduced and future diagnostic ultrasound equipment. The output display provides the user an indication of the potential for bioeffects that might be caused by the ultrasound energy being emitted. With this information, users can better control the diagnostic ultrasound equipment and examination to assure that needed diagnostic information is obtained with a minimum of risk to the patient.

To get the most benefit from the output display, the user should have a basic understanding of the nature of ultrasound-induced bioeffects, how to conduct an exam that minimizes the potential for bioeffects, and how to operate the controls of the equipment used in the exam.

This brochure is divided into three parts. Part One describes ultrasound-induced bioeffects and why we should be concerned about them. Part Two describes the risks and benefits of conducting diagnostic examinations and introduces the concept of ALARA, that is, ultrasound exposure As Low As Reasonably Achievable. Using ALARA, we can obtain needed diagnostic information with minimum risk to the patient. Part Three describes how to implement ALARA on equipment with and without an output display. With an output display, we have the best information about the potential for bioeffects and can make the best decisions.

Each manufacturer's equipment has somewhat different control features. This brochure can only provide general principles about ALARA and diagnostic ultrasound equipment. Please refer to the user documentation for your particular equipment to learn the details of its particular controls and output displays.

Acknowledgements

The development of this Ultrasound Education Program brochure went through a number of style and format changes and involved dedicated professionals from a number of organizations over the past three years. Initially, three videotapes were planned with the creation of three scripts. What finally emerged is this brochure. There are many individuals to thank. Special recognition is given to Mr. Chas Burr for his extensive revisions to the final content of the text. Without their assistance, this brochure would not have been possible.

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September 1994

Part One
Bioeffects and Biophysics

"Diagnostic ultrasound has proven to be a valuable tool in medical practice. An excellent safety record exists in that, after decades of clinical use, there is no known instance of human injury as a result of exposure to diagnostic ultrasound. Evidence exists, however, to indicate that at least a hypothetical risk for clinical diagnostic ultrasound must be presumed."

Radiological Health Bulletin,
Vol XXIV, No. 8,
August 1990

Chapter One
Is It Safe?

Issues Addressed:

- Why it is important to know ultrasound physics
- What dose-effect studies tell us
- Mechanisms of ultrasound-induced biological effects
- History of ultrasound
- Prudent use

Q. Everyone thinks that ultrasound is safe. We keep hearing, "no known instance of human injury as a result of exposure to diagnostic ultrasound." So why do we have to learn about biophysics and bioeffects?

Everyone thinks ultrasound is safe.

A. When ultrasound propagates through human tissue, there is a potential for tissue damage. There has been much research aimed at understanding and evaluating the potential for ultrasound to cause tissue injury. Through these studies, we are trying to learn what causes ultrasonic bioeffects and apply that information to diagnostic ultrasound. Many studies are dose-effect studies. These laboratory studies give us two things: First, they provide an opportunity to use much higher dosage levels than those currently used in a diagnostic ultrasound exam to really test the safety of ultrasound, and second, they permit a detailed study of mechanisms thought to be responsible for bioeffects.

There is a potential risk.

Q. So dose-effect studies are performed at higher intensities than diagnostic ultrasound?

Dose-effect studies

A. Much higher levels. In fact, virtually all ultrasonically induced adverse biological effects have occurred at these higher intensity levels.

Q. What's been learned from the dose-effect studies?

A. So far, we've deduced that two mechanisms are known to alter biological systems. One, called the "Thermal Mechanism," refers to heating of soft tissue and bone. The other, "Nonthermal," involves mechanical phenomena such as cavitation, although nonthermal mechanisms are more than cavitation alone. You can think of cavitation as the interaction of ultrasound with tiny bubbles in tissue and liquids.

Thermal Mechanism
Nonthermal Mechanism

History of ultrasound

Q. How long have we known of the potential hazards of ultrasound?

A. In 1880, two French scientists, Jacques and Pierre Curie, discovered piezoelectricity, the basis for ultrasonic transducers. About thirty-five years later, another French scientist named Paul Langevin developed one of the first uses of ultrasound, underwater sound-ranging of submerged objects known today as sonar. In the process he discovered and reported that very high intensity ultrasonic levels could have a detrimental effect on small aquatic animals.

Ten years later, scientists Wood and Loomis conducted experiments that substantiated Langevin's observation. Then, in 1930, Harvey published a paper about the physical, chemical, and biological effects of ultrasound, reporting that alterations were produced in a variety of organisms, cells, tissue, and organs. Long before anyone even thought of using ultrasound to produce images of the human body, it was already known that high levels of ultrasound were hazardous. With this in mind, early pioneering engineers and clinicians who were designing ultrasound imaging devices knew about the potential for disrupting biological tissue.

Thus, there has been concern about potential harmful effects throughout the entire period of diagnostic instrumentation development.

If there's a potential for bioeffects . . .

Q. If there's a potential for bioeffects, why do we use ultrasound?

No patient injury has ever been reported from diagnostic ultrasound.

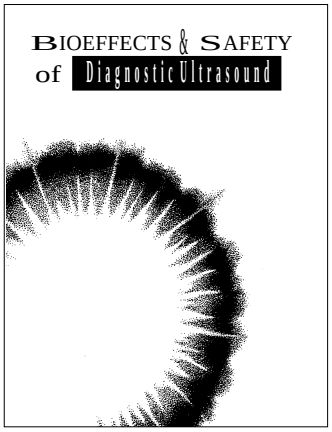
A. Most important, we use ultrasound because of its many diagnostic uses and benefits. Although there may be a risk, there has never been a documented instance of a patient being injured from this diagnostic modality.

Q. If there is a potential for ultrasound-caused bioeffects, why has there been such a good safety record?

Diagnostic ultrasound equipment is regulated by the FDA.

A. As the uses of medical devices have grown and more application areas and equipment have been developed, regulations have been enacted to provide for patient safety concurrent with equipment development. In 1976, the Medical Device Amendments to the Food, Drug, and Cosmetic Act were enacted requiring the Food and Drug Administration (FDA) to regulate all medical devices, including diagnostic ultrasound equipment. The FDA has required manufacturers of diagnostic ultrasound equipment to keep acoustic output below that of machines on the market before 1976, the year the amendments were enacted. Manufacturers bringing new products to market must compare the various performance characteristics of ultrasound equipment, including acoustic output, to devices previously approved for marketing.

Within these "limits," ultrasound has shown itself to be a safe and effective diagnostic tool for medical application. But it is important to remember that the pre-1976 output levels are based in history, not on scientific safety evaluations.



In March 1993, the American Institute of Ultrasound in Medicine approved the Official Statement on Clinical Safety:

"Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use: No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."

". . . the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present."

(From *Bioeffects and Safety of Diagnostic Ultrasound,* published in 1993 by the American Institute of Ultrasound in Medicine)

Q. Why is there more discussion of ultrasound safety now than in the past?

History of ultrasound in medicine

A. The question of safety is being discussed more because more and more applications are being found, and the industry is producing technically sophisticated devices that provide more diagnostic information. Current dialogue among the medical community, manufacturers, and the FDA suggests that new standards recently developed should allow higher outputs for greater diagnostic capability. This will improve some imaging and Doppler situations, but with greater risk and greater operator responsibility.

Higher outputs bring potentially greater risk.

Just because we haven't detected bioeffects on humans at diagnostic levels, doesn't mean that they don't exist. We know the potential for risk exists. It's important for ultrasound users to know about biophysics and bioeffects so they can make informed decisions about the use of ultrasound and can reduce the chances of bioeffects occurring. In the future, more and more decisions about the use of ultrasound output levels will be made by equipment operators.

Prudent use

The use of ultrasound in medicine began in the 1950s. At that time, the number of applications was rather limited. The uses for ultrasound grew in the 1950s, adding applications such as cardiology, obstetrics, gynecology, vascular, ophthalmic, and the imaging of regions of the

body, such as the female breast and male pelvis. By the early 1960s most of the basic ultrasound applications used today had been attempted, although with much less diagnostic content than today. Clinical use continued to grow during the 1970s with the introduction of real-time scanning.

Early exams were conducted entirely through the skin surface, but intracavitary and intraoperative applications have undergone a recent surge as manufacturers and clinicians seek to expand the diagnostic potential of ultrasound. Today, the clinical uses for ultrasound are many and varied, and diagnostic ultrasound is one of the fastest growing imaging techniques in medicine. Surveys in the United States indicate that a very high percentage of pregnant women are scanned to obtain fetal health information. There are about 100 thousand medical ultrasound scanners in use worldwide. This equipment handles millions of examinations each year. And, the number continues to grow.

Chapter Two
Thermal Bioeffects

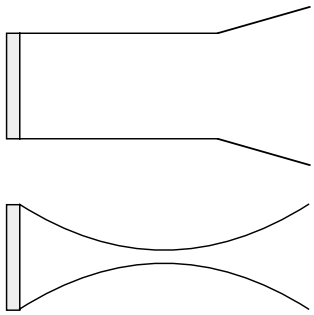
Issues Addressed:

- Focused and unfocused ultrasound fields
- Spatial and temporal considerations
- Attenuation, absorption, and scattering
- Soft tissue, layered and fetal bone models
- Soft tissue, layered and fetal bone heating
- Axial temperature increase profiles

Q. If ultrasound causes tissue temperature to rise, where is the largest temperature rise found?

A. The highest temperatures tend to occur in tissue in the region between where the ultrasound beam enters tissue and the focal region.

Because the temperature elevation is related to both ultrasonic power and the volume of exposed tissue, we need to keep in mind whether the beam is scanned or unscanned, in other words, whether the equipment moves the beam or keeps it stationary. Scanned modes, such as B-mode imaging and color flow Doppler, distribute the energy over a large volume. In scanned modes, the highest temperature is frequently at the surface where the ultrasound enters the body.



Unfocused and focused ultrasound fields.

Unscanned modes, such as spectral Doppler and M-mode, concentrate the power along a single line in the patient and deposit energy along the stationary ultrasound beam. Energy is distributed over a much smaller volume of tissue than in the scanned case. In unscanned modes, the highest temperature increase is found between the surface and the focus. In other words, the hottest point is along the center axis of the beam and proximal to the focal point, but not at the focal point. The exact location depends on the tissue attenuation and absorption properties and the beam's focal length. For long focal lengths, the location of the maximum temperature elevation may lie closer to the surface, but for short focal lengths, it is generally closer to the focus.

Q. Focusing the ultrasound beam increases the temperature?

Spatial considerations

A. Focusing concentrates the power in the beam on a small area, thereby improving image lateral resolution, but also causing higher intensities and the potential for higher temperatures.

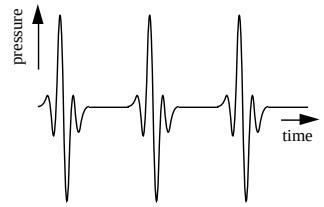
$$\text{Intensity} = \frac{\text{Power}}{\text{Area}}$$

Q. What other aspects of the ultrasound beam affect the temperature?

Temporal considerations

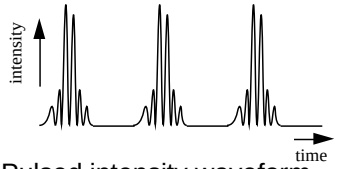
A. An important aspect is time.

Ultrasonic waves can be emitted in pulsed wave form. There's a burst of energy, then, there's a period of silence. Then, there's another pulse and more silence, and on and on. During the pulse the acoustic intensity is high, but during the silence the intensity is zero.



Pulsed pressure waveform

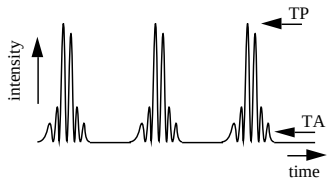
If we take the entire repeating time period, both the pulse and the silence, and average the intensity of the ultrasound over time, we come up with a temporal-average intensity that may be a thousand times smaller than the instantaneous or temporal-peak intensity that occurs once during the pulse. Bioeffects resulting from temperature increases depend, in part, on the temporal-average intensity.



Pulsed intensity waveform

The intensity at the location of the greatest temporal-average intensity is referred to as the spatial-peak temporal-average intensity: SPTA. The SPTA is often used as a specification of ultrasound output.

In addition to time averaging, there's another time concept that affects temperature increase: duration of the ultrasound exposure, or how long one location is imaged during an examination. It takes time for tissue temperature to rise, and the longer the exposure duration, the greater the possibility of a biological effect.



Temporal-average (TA) and temporal-peak (TP) intensities

Ultrasound exposure duration

Q. What causes the temperature rise in tissue during ultrasonic exposure?

A. The absorption of energy. During an exam, much of the ultrasound energy is absorbed by body tissue. If the rate of energy deposition in a particular region exceeds the body's ability to dissipate the heat, the local temperature will rise.

Attenuation
1. Absorption = energy converted to heat
2. Scattering = redirection of ultrasound

Absorption and attenuation are often confused. Attenuation is the loss of energy from the propagated ultrasound wave. There are two causes for attenuation: Absorption and scattering. Absorption is the conversion of ultrasonic energy into heat; whereas, scattering is the redirection of the ultrasound away from the direction it was originally traveling.

Absorption of acoustic energy by tissue results in the generation of heat in the tissue. This is what is referred to as the thermal mechanism. There are a number of physical and physiological variables that play a role in absorption and the generation of temperature increases. Some, of course, are the operating characteristics of the equipment. For now, let's concentrate on physical parameters.

Q. What are some of the physical parameters that affect absorption?

A. The ultrasound energy is absorbed by tissue, at least to some extent.

The extent depends on the tissue, on what we call tissue absorption characteristics.

Attenuation coefficient and absorption coefficient have the same units—dB/cm or dB/cm-MHz

A specific way in which tissue absorption characteristics are quantified is with the "Absorption Coefficient." The absorption coefficient is expressed in decibels per centimeter. Since absorption coefficient is directly proportional to ultrasonic frequency, the coefficient is often normalized to frequency and represented as decibels per centimeter per megahertz. Absorption coefficients are very dependent on the organ or tissue type that is being imaged.

Increasing Attenuation Coefficient
Water
Biological fluids
Soft tissues
Skin and cartilage
Fetal bone
Adult bone

Q. Let's get some examples. What's the absorption coefficient of, say, fluids, like amniotic fluid, blood, and urine?

A. Almost zero. These fluids absorb very little ultrasonic energy. That means the ultrasound goes through the fluid with very little decrease. And there's little temperature elevation in the fluid.

Q. Which body tissue absorbs the most energy?

A. Bone. Its absorption coefficient is very high. Dense bone absorbs the energy very quickly and causes the temperature to rise rapidly. Adult bone absorbs nearly all of the acoustic energy impinging on it. Fetal bone absorption coefficients vary greatly depending on the degree of ossification.

Q. Now what's between fluid and bone?

A. Soft tissue. Tissues vary in density depending on the particular organ, but the density doesn't vary much within a organ. We call it soft to distinguish it from hard tissue such as bone. It's also true that the tissue density within a particular organ is not always the same. But, for our purposes we assume that attenuation and absorption are uniform throughout the organ. We call this a homogeneous soft tissue model.

Homogeneous soft tissue model

Q. How does frequency affect absorption?

A. The higher the frequency, the higher the absorption. What that means to operators is that a higher-frequency transducer will not allow us to "see" as far into the body.

Q. Does that mean that higher-frequency transducers create more heat?

Higher Frequency = Increased Absorption, Reduced Penetration, Possible Near Surface Heating

A. Not necessarily. There are many factors that contribute to creating heat. However, if all other factors are equal, the ultrasound energy of higher-frequency transducers is absorbed more rapidly than that of

lower-frequency transducers, thereby causing reduced penetration. In some cases, this may introduce increased heating near the skin surface.

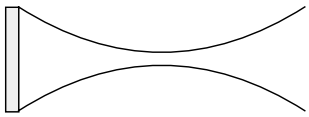
However, due to the rapid absorption of higher-frequency ultrasound, there's another indirect effect that might occur. If we're not getting deep enough, we might choose to increase the output, and the increased intensity could also increase temperature.

Q. Now let's talk about what all this means in practical terms. What is the situation of most interest?

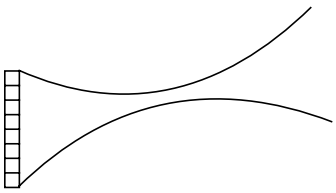
A. The situation of greatest interest involves the fetus with ossified bone (second and third trimester) and a mother with a thin abdominal wall. Because there would be little absorption of energy between the transducer and the fetus, nearly all of the energy would be absorbed by a fetal bone, if the beam is focused on or close to it.

Q. What can we as operators do to minimize temperature rise?

A. First, temperature increases depend on intensity, duration of exposure at the same location, transducer focal point size and location, and absorption of the energy by the tissue. In general, intensity is alterable, and depends on the particular equipment we're using. As the operator, we can also control duration, or exposure time. The transducer is typically moved frequently during the exam, which will naturally reduce the exposure duration at a specific tissue location.



Fixed-focus transducer



Multi-element array transducer

Let's look at the other two factors: transmit focal point and absorption. A highly focused beam whose focal point is in the amniotic fluid will not cause significant heating of the fluid, because its absorption coefficient is low. If the focus is in tissue, all things being the same, the temperature rise is a little higher. However, the same beam will cause an even higher temperature rise time if it focuses on bone, which has a much higher absorption coefficient. Be aware that there are fixed-focused transducers whose focus we can't change and multi-element array transducers whose focus we can change.

The other important determinant of local temperature rise is absorption of ultrasound energy in tissue layers in front of the point of interest. Increased absorption in these layers decreases the ultrasound energy available at the point of interest. For example, an obstetrical examination of a patient with a thick abdominal wall is less likely to cause a significant temperature increase in the fetus than an examination through a thin abdominal wall.

Q. What are some examples of temperature increase calculations?

A. We have computer models that predict the relationship between transducer focus and changes in the temperature curve.

Computer Tissue Models

- Homogeneous Soft Tissue Model
- Layered Tissue (Fluid-filled Bladder) Model
- Fetal Bone Model

Assumptions

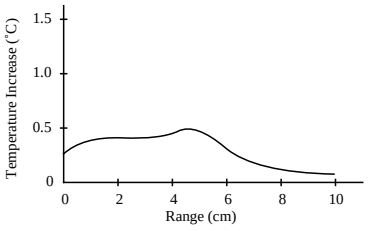
- Speed of Sound Is Uniform Throughout
- Attenuation Is Uniform Throughout
- Absorption Is Uniform Throughout
- Absorption Equals Attenuation (Scattering is negligible)

Modeling various tissue layers is difficult since there are so many. We focused on two simplified models. In the first, ultrasound travels through homogeneous soft tissue. In the second, ultrasound travels through a fluid-filled bladder. We assumed that the speed of sound, acoustic impedance, attenuation, and absorption are uniform throughout the volume of interest.

Transducer

- 3.0 MHz
- 19 mm diameter
- 6 cm transmit focal length
- 100 mW output ultrasonic power

We also selected a 3.0 MHz, 19 mm diameter transducer with a 6 cm transmit focal length. For convenience, we have used an ultrasonic output of 100 mW for our example. This is a relatively high output level for today's diagnostic equipment, only found in some Doppler and color Doppler modes. Keep in mind, these models are for educational purposes and may not reflect actual clinical situations.



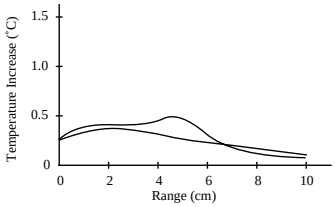
Homogeneous soft tissue model: axial temperature increase profile for a transmit focal length of 6 cm

Homogeneous Tissue Model: Abdominal Exam

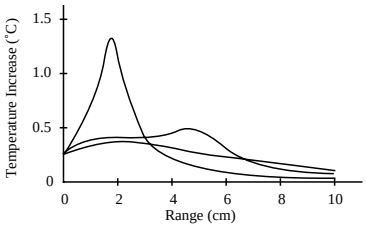
First, let's look at the homogeneous tissue model. This model is similar to the situation in an abdominal exam involving soft tissue only. The temperature increase in degrees Celsius goes up the left side of the figure. The range in centimeters goes across the bottom of the figure.

We'll see that the temperature increase exhibits a maximum at about five centimeters.

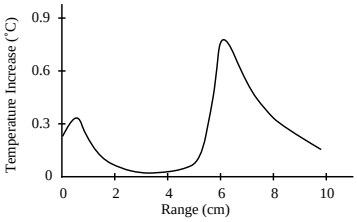
For the next scenario, all we'll change is the focal point location. We just saw the 6 cm focal length. Now, let's see what the same transducer does in the same tissue with a 10 cm focal length. It flattens out quite a bit, doesn't it?



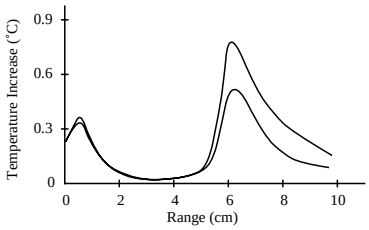
Homogeneous soft tissue model: axial temperature increase profile for a transmit focal length of 6 and 10 cm



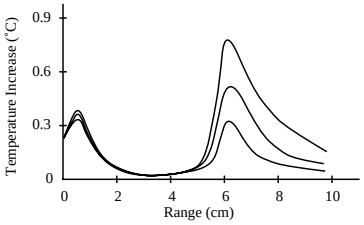
Homogeneous soft tissue model: axial temperature increase profiles for transmit focal lengths of 2, 6, and 10 cm



Layered tissue model: axial temperature increase profile for a transmit focal length of 6 cm



Layered tissue model: axial temperature increase profile for transmit focal lengths of 6 and 10 cm.



Layered tissue model: axial temperature increase profile for transmit focal lengths of 4, 6 and 10 cm.

But look at what happens if the focal length is 2 cm. The temperature goes way up to about 1.3˚C at a range of about 2 cm. What does that mean? It means that a significant increase in temperature near the beam's focus is more likely with shorter focal lengths because less overall attenuation of the beam has occurred.

Now, let's look at this in a situation similar to an obstetrical exam.

Layered Tissue Model: Obstetrical Scan

- Abdominal wall thickness = 1 cm
- Bladder fluid path = 5 cm

For this situation, we have a layered tissue model based on an obstetrical scan through the abdominal wall and through the fluid-filled bladder to the fetus. For the scenario, we assumed a patient with a thin abdominal wall of 1 cm and a 5 cm fluid path. The transducer and its ultrasonic power are the same as those used in the homogeneous tissue cases. The transmit focal length of 6 cm is at the location of the far side of the bladder and note that the temperature goes up to about 0.8˚C at this range. Also note, the increase in temperature in the abdominal wall is about 0.4˚C. There's almost no absorption of ultrasound in the bladder fluid, so little heat is produced there.

Now here's the axial temperature increase profile in the layered tissue model for a longer focal length of 10 cm. The temperature rise at the far side of the bladder is about 0.5˚C, a drop from when the ultrasound beam was focused at that location.

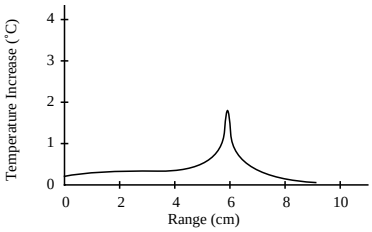
Let's look at a situation where the beam focuses in front of the far side of the bladder, at a 4 cm transmit focal length. The temperature rise at the far side of the bladder is about 0.3˚C, also a drop from when the ultrasound beam is focused at that location. Note that the increase in temperature in the abdominal wall is about 0.4˚C for all three focal length conditions.

That means if the transmit focus location occurs before the target, then the temperature rise at the far side of the bladder, at a range of 6 cm for this layered tissue model, is less than if the focus is at or beyond the target, where the temperature elevation at the target is higher.

Fetal Bone Model

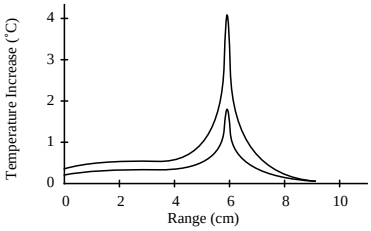
- Homogeneous Soft Tissue Parameters
- Bone Location at 6 cm in Range
- 100 mW Output Ultrasonic Power

Let's see what happens when we focus near bone. For this model, we'll use the homogeneous soft tissue parameters for the tissues through which the beam passes, but our reflective surface is bone that is perpendicular to the beam at a range of 6 cm. We will also use the same output ultrasonic power of 100 mW. When the transmit focal range is beyond the location of bone, focal range of 10 cm, there is a peak in the temperature increase to about 1.9˚C at the bone location.



Fetal bone model: axial temperature increase profile for a transmit focal length of 10 cm

Here's what happens with a transmit focal length of 6 cm, that is, the ultrasound beam is focused on the bone surface: a theoretical temperature rise of about 4.2˚C.



Fetal bone model: axial temperature increase profile for transmit focal lengths of 6 and 10 cm

Q. How does all this apply to actually scanning a patient? Is this dangerous?

A. Potentially dangerous. The examples we looked at are for educational purposes and do not necessarily occur in clinical situations. For example, the output power used for the calculation would not be commonly used, but it is within the capability of many systems.

Temperature rise during an actual examination depends on many factors. For example, very few patients have as thin an abdominal wall as we assumed in this model. In addition, the exposure to bone must be continuous over time for local temperatures to rise. That seldom happens in actual exams. Plus, some heating is lost due to the cooling effect of local blood flow. To date, there is no evidence of any harm in humans from thermal effects at the output levels of current ultrasonic devices.

Abdominal wall thickness,
Focal length and location,
Exposure duration,
Bone attenuation,
Tissue attenuation,
Bone absorption, and
Tissue absorption

Q. But if it's potentially dangerous, why hasn't there been an incident?

A. The combined conditions required to produce these heating effects are unlikely to occur. In addition, the control parameters on current equipment are designed to limit the temporal-average intensity. By minimizing temporal-average intensity, significant thermal effects in the body are not likely to occur. However, it is unclear what output levels will be used in future applications and equipment.

The goal is to get an image that provides <u>necessary</u> diagnostic information. If we are overly cautious, we may end up with poor image quality or inadequate Doppler signals. For operators to minimize the risk, we need to understand the factors that contribute to temperature rise, for example, the thickness of the mother's abdominal wall, the beam focal length and location, exposure duration, and the attenuation and absorption characteristics of tissue and bone.

The goal is to get an image that provides necessary diagnostic information.

Chapter Three
Nonthermal Bioeffects

Issues Addressed:

- Onset of cavitation
- Peak compressional pressure
- Peak rarefactional pressure
- Stable cavitation and transient cavitation
- Microstreaming
- Nucleation site
- Threshold phenomenon

Q. Nonthermal bioeffects means bioeffects not caused by temperature rise. That tells us what they are not. Exactly what are nonthermal bioeffects?

A. Nonthermal bioeffects are not as well understood as thermal effects. They are sometimes referred to as mechanical bioeffects because they seem to be caused by the motion of tissue induced when ultrasound pressure waves pass through or near gas. The majority of the nonthermal interactions deal with the generation, growth, vibration, and possible collapse of microbubbles within the tissue. This behavior is referred to as cavitation.

Cavitation was first discovered around the turn of the century, not in tissues, but at the surface of a ship's propellers. Researchers found that the low-pressure region immediately behind a ship's propellers caused bubbles to be produced in the water. The collapsing bubbles damaged the propellers. The bubbles collapsed violently, generating shock waves that eroded the propeller blades.

What is cavitation—bubbles?

Q. So cavitation is bubbles?

A. With diagnostic ultrasound, cavitation refers to ultrasonically induced activity occurring in tissues or body liquids that contain bubbles or pockets containing gas or vapor. These bubbles originate within materials at locations termed "nucleation sites," the exact nature and source of which are not well understood in a complex medium such as tissue or blood.

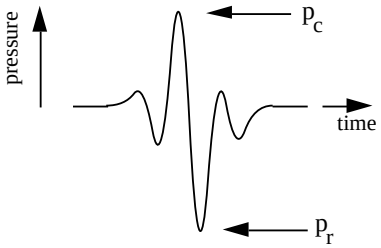
Positive pressure = Compressional pressure

Negative pressure = Rarefactional pressure

A sound wave has positive pressure and negative pressure. Positive pressure is also called compressional pressure; negative pressure is also called rarefactional pressure. If the rarefactional pressure is sufficiently large, microbubbles may be produced, or existing microbubbles may be enlarged.

Q. When does cavitation occur?

A. The occurrence of cavitation and its behavior depend on many factors, including the ultrasonic pressure and frequency, the focused or unfocused and pulsed or continuous ultrasonic field, the degree of standing waves, and the nature and state of the material and its boundaries.



Peak compressional pressure (p_c) and peak rarefactional pressure (p_r)

Cavitation depends on
- frequency
- pressure
- focused/unfocused beams
- pulsed/continuous ultrasound
- degree of standing waves
- nature and state of material
- boundaries

Q. Is cavitation related to SPTA intensity?

A. No. The correlation is not with temporal-average intensities, but rather with pressure. Cavitation is most closely related to peak negative pressure, or peak rarefactional pressure, during the pulse.

Peak negative pressure is roughly related to the pulse-average intensity. So, the spatial-peak pulse-average intensity, the SPPA intensity, is loosely related to cavitation. This relationship is useful to us because many existing ultrasound systems use SPPA intensity as a specification or control.

Q. Are there different types of cavitation?

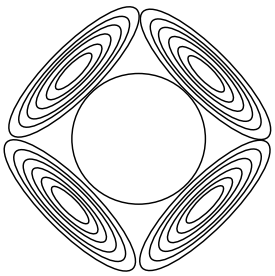
A. Cavitation can be discussed in terms of two categories: stable cavitation and inertial (or transient) cavitation.

Cavitation is related to the peak rarefactional pressure.

Stable cavitation is associated with vibrating gaseous bodies. In stable cavitation a gaseous body remains stabilized and, because of the ultrasonic field, oscillates or pulsates. As the oscillations become established, the liquid-like medium around the gas bubble begins to flow or stream; we call this “microstreaming.” Microstreaming has been shown to produce stress sufficient to disrupt cell membranes.

Cavitation
1. Stable
2. Inertial (or Transient)

During inertial cavitation, pre-existing bubbles or cavitation nuclei expand from the pressure of the ultrasonic field and then collapse in a violent implosion. The whole process takes place in a very short time span that is on the order of microseconds. The implosion can produce huge local temperature rises that may be thousands of degrees Celsius, and pressures equal to hundreds of atmospheres all in an area that is less than one square micrometer. The implosion can damage cells and tissue, ultimately leading to cell death. In addition, bubble implosion can generate highly reactive chemical species. All of these effects, microstreaming, implosion, and reactive chemicals occur in a very small space around the bubble, affecting only a few cells.


Oscillating bubble and microstreaming

Q. Is it really possible for cavitation to occur at the amplitudes and frequencies used for diagnostic ultrasound?

A. Perhaps, if nuclei sites are available. There is ample theoretical and some experimental evidence to support this conclusion, and that biological alterations can occur. We are fortunate to have this evidence because it documents the levels above which cavitation is thought to occur, and because there is a lot of scientific evidence to suggest that the onset of transient cavitation is a threshold phenomenon.

There's a combination of rarefactional pressure values, ultrasonic frequency, and cavitation nuclei that are required for cavitation to occur. If, as evidence suggests, cavitation is a threshold phenomenon, then exposure to pressure levels below the threshold for cavitation will never induce cavitation, no matter how long the exposure lasts.

Can cavitation be produced by diagnostic ultrasound equipment?

Q. Do we know of any incidence of cavitation occurring in human tissue or fluids resulting from diagnostic ultrasonic exposure?

A. Currently, there is no evidence that diagnostic ultrasound exposure has caused cavitation in humans.

In addition, the control parameters on current equipment limit the peak output. However, limits may be raised or eliminated in future equipment.

Q. But, theoretically, it can happen?

A. Yes. But since cavitation would probably affect only a single cell, or a few cells, it is extremely difficult to detect an adverse biological effect, unless the cavitation events were widespread among a large volume of tissue.

Part Two
Prudent Use

"Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to the patient of the *prudent use* of diagnostic ultrasound outweigh the risks, if any, that may be present."

American Institute of Ultrasound in Medicine
Official Statement On Clinical Safety
March 1993

Chapter Four
Benefits And Risks

Issues Addressed:

- Risks versus benefits
- Diagnostic ultrasound benefits
- Risk of not performing the study
- Prudent use
- New technology and applications
- High output, potentially greater risk
- High output, potentially greater diagnostic capability
- Shifting responsibility

Risks vs. benefits

Q. "Risks versus benefits." What do we mean by that in terms of ultrasound?

A. The risks are the potential for adverse bioeffects caused by heating or cavitation. Although there has not been a reported incident of serious bioeffects on humans at diagnostic ultrasound levels, we do know that heating of the tissue may occur and there may be the potential for cavitation to occur.

The benefit is the diagnostic information ultrasound provides. And ultrasound imaging provides very good data, data that allow physicians to make clinical decisions. With information from an ultrasound exam, physicians can weigh alternative courses of action and select the best method for helping the patient.

Ultrasound imaging is popular first and foremost because it's a superb diagnostic modality. It provides tremendous diagnostic information with great sensitivity and specificity. But it's also a favorite imaging technique because it appears safe, is widely accepted by patients, is portable, and is relatively low in cost compared to other diagnostic imaging modalities. Physicians must weigh the expected benefit from a diagnostic ultrasound procedure against the potential risks of that procedure.

Examples of benefits from diagnostic ultrasound: Cardiac studies

Q. What are some examples of the benefits of diagnostic ultrasound?

A. Let's look at ultrasound in cardiac studies. The use of diagnostic ultrasound for cardiac applications has increased dramatically over the past ten years. From M-mode scans to transesophageal echocardiography, ultrasound gives us the ability to image the structure and function of the heart and great vessels in exquisite detail. Ultrasound also has the ability to follow the normal and abnormal course of blood flow within the heart.

Q. How about potential bioeffects with some of the new cardiac applications?

A. Diagnostic ultrasound has an excellent safety record over the years that it's been used to study the heart. The nature of many cardiac ultrasound techniques, the variety of imaging windows, and the fact that the heart is filled with moving blood means that the duration of the exposure of any one area of the heart is reduced.

It's a real risk not to perform the study.

Newer applications of ultrasound through the esophagus and within the vascular space may result in bioeffects we've not previously known about. We need more research before we can define all the risks. But remember, the physician should weigh potential bioeffects against the real risks of not doing the study and missing important timely diagnostic information.

Q. What other medical specialties benefit from ultrasound?

Example of benefits from diagnostic ultrasound: Obstetrical exams

A. Ultrasound has had a huge impact on the area of obstetrics. The use of ultrasound examinations during pregnancy has increased dramatically since the 1970s. The use of ultrasound in obstetrics is a principal area of concern for potential bioeffects. Ongoing studies may provide accurate information related to potential effects of ultrasound on the embryo–fetus. In fact, the combination of the increase in use and the concern for safety led to the National Institutes of Health consensus development conference in the early 1980s. The conference discussed the use of diagnostic ultrasound in pregnancy. The committee did not recommend routine ultrasound examinations during pregnancy, but they did suggest a number of appropriate clinical indications for the use of ultrasound imaging during pregnancy.

Balancing benefits and risks

Q. How do you balance the benefits and risks?

Ultrasound benefits:
- Many diagnostic uses
- Replaces or used with other procedures
- Cost effective
- Patient acceptance
- High quality information

A. Ultrasound imaging during pregnancy is important because it provides a considerable amount of information. On the one hand, ultrasound offers lots of diagnostic uses, may be used to replace some procedures, can be used in conjunction with other procedures, is cost effective, is accepted by patients, and provides a great deal of high quality clinical information.

Prudent use

On the other hand, we have the risks: thermal and nonthermal bioeffects. But there's another risk that must be considered: the risk of not doing the ultrasound exam and either not having the information or having to get it in a less desirable or invasive way. As the American Institute of Ultrasound in Medicine statement says, "*. . . the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.*"

Q. What about the benefits of new ultrasound technology and applications?

New technology and applications

A. There has been a virtual explosion of technology and applications over the past few years: new manufacturers, new products, new medical specialties, and more and more medical applications. Now we have everything from small hand-held Doppler systems that follow blood flow in peripheral vessels to more general imaging systems that display nearly all of the body's soft tissues in detail.

But it's more than technology; it's what that technology gives us; for instance, better quality images and more diagnostic information. Still, all the operating modes and the varying output levels mean that more responsibility must be assumed by the users.

Users assume more responsibility

Diagnostic ultrasound is widely accepted because it is a superb diagnostic tool with an excellent history of safety. We want to keep it that way. But with more and different types of equipment, larger numbers of patients, and all the new applications, there's increased concern about potential bioeffects.

Q. Now that we understand the potential for ultrasound-induced bioeffects, should we change how we use the equipment?

A. We must learn to balance the risks and the benefits. We have learned about bioeffects: thermal effects, or tissue heating; and mechanical effects, such as cavitation. We learned how intensity, exposure time, focal properties, and pressure are associated with the risk for bioeffects. Using too much intensity can increase the risks, but using too little intensity for the clinical situation can lead to poor images and the loss of essential information.

When we use ultrasonic devices, we should remember the safety concerns. Ultrasound should neither be used as a "toy" or without clinical need, nor should it be considered as "perfectly safe." We know and have known for more than 75 years that ultrasound, at certain levels, can alter biological systems. There will always be a need for continued awareness of future research findings. But we also know that one should not hesitate to have a diagnostic ultrasound examination when there is clinical benefit to be derived.

Q. In the future, might there be increased risk as well as increased benefit?

Future benefit vs. risk

A. The future may be quite different. If existing acoustic output limits were removed, the primary responsibility for the safety of acoustic output would shift from design restrictions, as on current diagnostic

ultrasound devices, to the judgement of the users. In return for potentially enhanced diagnostic capabilities, we will have to balance the clinical need against the risk of an adverse bioeffect. We will need a knowledge of the thermal and mechanical mechanisms, the bioeffects of ultrasound, the ultrasound output levels being used, and the relationship of output level to image quality.

Chapter Five
ALARA

Issues Addressed:

- The ALARA principle
- Controlling ultrasonic energy
- Controlling exposure time
- System capability and ALARA
- Operating mode and ALARA
- Transducer capability and ALARA
- System setup and ALARA
- Scanning technique and ALARA

Q. Knowing that ultrasound energy is related to potential bioeffects, how can we reduce the risks?

A. We have a simple principle that we can apply to the use of ultrasound energy. It's called ALARA, which stands for "As Low As Reasonably Achievable." Following the ALARA principle means that we keep total ultrasound exposure as low as reasonably achievable, while optimizing diagnostic information.

ALARA, or As Low As Reasonably Achievable

With new ultrasound equipment, the output display lets us determine the exposure level in terms of the potential for bioeffects. For equipment that does not have an output display, we depend on whatever output information, such as intensity, dB, or percentage of power that the system provides.

Users control the total exposure to the patient.

Because the threshold for diagnostic ultrasound bioeffects is undetermined, it becomes our responsibility to control the total exposure to the patient. Controlling the total exposure depends on output level and exposure time. The output level required for an exam depends on the patient and the clinical need. Not all diagnostic exams can be performed at very low levels. In fact, using too low a level may result in poor data and the need to repeat the examination. Using too high a level may not increase the quality of the information, but it will expose the patient to unneeded ultrasound energy.

Q. If output level depends on the patient and the clinical need, what determines exposure time?

What determines exposure time?

A. Ultimately, the exposure time depends on the person conducting the exam. Primarily, it's our training, education, and experience that determine how quickly we can obtain a useful image, and thus, the length of the exam and the amount of exposure. So, the question is, "How much time do we need to obtain the desired diagnostic information?"

System Capabilities:
Operating mode
Transducer capabilities
System setup
Scanning techniques
Knowledge and experience

But there are also some other factors that might affect the length of time that any particular tissue is exposed. One is the mode, whether it's a moving or a stationary beam; and another is the choice of transducer. Other factors include the patient's body characteristics, the operator's understanding of the controls on the system and how they affect output levels, and whether it's continuous wave or pulsed Doppler, or color flow Doppler. To achieve ALARA, we need a thorough knowledge of the imaging mode, transducer capabilities, system setup, and operator scanning techniques.

Operating mode:
B-mode
M-mode
Doppler
Color flow Doppler

System capabilities include the following: mode, transducer capabilities, system setup, and scanning techniques. Let's talk about each. First, the mode we select, such as M-mode, B-mode, or Doppler, depends on what we're looking for. B-mode imaging gives anatomical information while Doppler and color flow Doppler modes give information about blood flow through vessels. M-mode gives information about how anatomical structures move in time.

Transducer capabilities:
Frequency
Penetration
Resolution
Field of view

Second, transducer capabilities relate to penetration at the frequency chosen, resolution, and the field of view that we can obtain with the selected transducer.

System setup:
Starting output power
Starting intensity outputs
Scanning results

Third, system setup and control settings depend on where we start on the output scale and on our knowledge of which combination of controls gets the best results.

Scanning techniques:
Anatomy and pathology
Ultrasound physics
Signal processing features
Recording and playback features

Fourth, the scanning technique we use is based on our knowledge of anatomy and pathology, of ultrasound physics, and of the equipment's signal processing features, plus our experience with a given scanning modality, such as sector, linear, and so forth. A system's recording and playback features let us reduce exposure time to just the time necessary to obtain a useful image. Analysis and diagnosis can be performed using recorded images rather than lengthy live imaging sessions.

ALARA is a simple concept and easy to understand. Implementing ALARA well, however, requires all of our knowledge and skills as diagnostic ultrasound users. In Part Three we will learn how many of the controls found on diagnostic ultrasound equipment can affect ultrasound output. Without an output display standard we must rely on that knowledge to estimate a patient's ultrasound exposure. With an output display standard we have a real-time indication of the exposure in terms of the potential for bioeffects. Either way, we implement ALARA by minimizing the exposure level and duration while being sure to obtain the necessary diagnostic information.

Part Three
Implementing ALARA

Chapter Six
Knobology

Issues Addressed:

- Basis of knobology
- Tradeoff between *in situ intensity* and image depth
- Operator controls and ALARA
- Prudent use
- Know the user's guide
- An example of implementing ALARA

Q. What should we know about equipment control features, "knobology", to implement ALARA?

A. Whether or not a diagnostic ultrasound system has an output display, the same types of controls are used to obtain the needed diagnostic images. We should understand how these controls affect acoustic output levels so we can use them to get the best image with the least exposure. In this chapter, we will learn about types of controls that are available on most ultrasound imaging equipment.

Q. How can the operator control ultrasound output?

Operator controls and ALARA

A. There are several external system controls the operator can adjust to improve the quality of the image and to minimize the output intensity. To understand how these controls are related to ALARA, let's divide them into three broad categories: First, controls that directly affect intensity. Second, controls that indirectly affect intensity. These are controls such as Mode, Pulse Repetition Frequency and others. When you change the setting for one of these controls, you may also be changing the intensity. Third, controls that do not affect intensity. We can think of the third category as "receiver controls." These are controls that affect the processing of ultrasonic echoes returned from the body.

These aren't "official" categories, but they help us understand how the knobs affect ALARA. In fact, each equipment manufacturer provides somewhat different sets of controls. By reviewing the user's guide for the equipment, we can determine the particular controls that perform the functions described here.

Let's look at controls that directly affect intensity. They are application selection and output intensity.

<u>Controls directly affecting intensity</u>
Application selection
Output intensity

Application selection

With application selection, we may choose from applications such as peripheral vessel, cardiac, ophthalmic, fetal imaging, and others. There may be different “ranges” of intensity output based on these applications. Selecting the right application range is the first thing you can do. For example, cardiac intensity levels are not generally recommended for performing a fetal scan. Some systems automatically select the proper range for a particular application, while others require a manual selection.

For equipment that does not have an output display, the maximum intensity for each application is regulated by the FDA. The FDA regulation is meant to limit ultrasonic output levels to ranges historically used for each application. But users have some choice in the matter; we are responsible for the proper selection of an application range.

For equipment with an output display, FDA currently regulates only the maximum output for the system. Manufacturers establish intensity ranges appropriate for typical patient examinations. However, within the system limits, users may override the application specific limits. We are responsible for being aware of the output level that is being used. We know the output level from the system’s real-time output display.

Output intensity or power

Another control that has a direct effect on intensity is, of course, output intensity. This control also may be called transmit, power, or output. Once the appropriate application range has been selected, the transmit intensity control increases or decreases the output intensity within the range. Most equipment allows you to select intensity levels less than maximum, say 25 or 50 percent. ALARA implies that you select the lowest output intensity that is consistent with good image quality.

Controls indirectly affecting intensity:
System mode
Pulse repetition frequency
Focusing depth
Pulse length
Transducer choice

Q. Which controls indirectly affect intensity?

A. The second group of controls is intended to change aspects of the transmitted ultrasonic field other than the intensity. However, because they change the field, the intensity is affected. Whether the intensity increases or decreases and by how much is difficult to predict.

System mode

The choice of B-mode, M-mode, or Doppler, for example, determines whether or not the ultrasound beam is stationary or in motion, which greatly affects the energy absorbed by the tissue. If the beam is moving, then each targeted tissue volume experiences the beam only for a fraction of the time, except near the transducer for sector scans. If the beam is stationary, then the period of time a targeted tissue volume in the beam receives ultrasound is increased.

Q. What about the pulse repetition frequency—PRF?

A. The number of ultrasound pulses in one second is referred to as the pulse repetition frequency. The higher the pulse repetition frequency, the more output pulses per second, increasing the temporal average intensity. There are several controls which have an effect on the pulse repetition frequency. For example, with some diagnostic ultrasound systems, if we decrease the focal range, then the system may automatically increase the PRF.

Pulse repetition frequency (PRF)

Q. Next on the list is focusing. How would focusing affect intensity?

Focusing depth

A. In focusing, the beam is narrowed in order to get a better lateral resolution, increasing the temporal average intensity. Most systems adjust their output to offset the effects of focusing, so they tend to maintain the same intensities. As an operator, we need to set the transducer focus at the depth of the structure we're examining. Different exams require different focal depths. Setting the transducer focus at the proper depth improves the resolution of that structure, and we don't need to increase intensity to see it better.

Q. What about pulse length?

Pulse length

A. Pulse length, sometimes called burst length or pulse duration, is the time the pulse is on. Often the longer the pulse, the greater the temporal-average intensity value, which both raises the temperature in the tissue and slightly increases the likelihood for cavitation. In pulsed Doppler, increasing the Doppler sample volume length usually increases the pulse length.

Q. Transducer choice is another factor that indirectly affects intensity. How?

Transducer choice

A. Tissue attenuation increases with transducer frequency. The higher the frequency, the higher the attenuation. That is, a higher-frequency transducer requires more output intensity to 'see' at a greater depth. In order to scan deeper at the same output intensity, a lower transducer frequency must be used. So, for deeper structures, if we find ourselves maximizing output and gain without obtaining good image quality, we may have to switch to a lower frequency.

Q. We are calling the third category Receiver Controls. We use these to improve image quality. They have no effect on output; they only affect how the ultrasound echo is received and processed. The controls include gain, TGC, video dynamic range, and post processing. Let's just look at one of these . . . system gain. How can we use receiver gain to implement ALARA?

Receiver Controls that affect the image only
Receiver gain
TGC
Video dynamic range
Post processing

Always increase the receiver gain first.

A. The receiver gain controls amplification of the return echo signal. To obtain good diagnostic information, we need a high return signal amplitude. This can be attained either by higher output, similar to talking louder, or by higher receiver gain, similar to a hearing aid with volume control. The need for gain is determined by tissue attenuation, that is, how much of the ultrasound is lost as it passes to the reflective surface and back to the transducer. In some cases, we control the receiver gain by setting the gain control or TGC. But in other cases, gain is automatically adjusted by the system when the user adjusts the output control. If the equipment has a receiver gain control, and we are searching for a weak signal, we should always increase the system's receiver gain first, then increase the power output. That way, we reduce the output required and make it less likely to use high acoustic intensities in the patient's body tissue. Remember, a low receiver gain may necessitate using a higher output, or result in suboptimal image quality.

Q. What is an example of the use of ALARA in a clinical exam?

A. Imagine we are getting ready to do a liver scan. It will involve the use of B-mode, color, and Doppler. Let's see how we would follow the ALARA principle to set up and conduct the exam.

Select transducer
Check output transmit setting
Adjust focus
Increase receiver gain
Adjust output transmit again

The first thing we need to do is select the appropriate transducer frequency. Next, we adjust the output intensity (or power) transmit setting. We check to make sure it is positioned at the lowest possible setting to produce an image. We adjust the focus to the area of interest, then increase the receiver gain to produce a uniform representation of the tissue. If we can obtain a good image by increasing the gain, we can lower the output and continue to increase the gain. Only after making these adjustments and if tissue penetration or echo amplitude levels are inadequate should we increase the output to the next higher level.

Minimize exposure time

After we have achieved a good B-mode image, then we can use color to localize the blood flow so we can position the Doppler sample volume. This allows us to locate the vessel of interest faster and that minimizes exposure time. Now that we have an image of the vessel, we position the range gate (or sample volume gate) over the vessel.

Adjust output transmit setting again

Now we check the Doppler trace. We adjust the power setting by setting the Doppler transmit intensity at the lowest possible level to produce a clear signal. We will make a few more adjustments, for example, adjusting the velocity scale. Now we increase the receiver gain to get a diagnostic signal. If maximum gain adjustments are inadequate, then we raise the output to the next higher level.

That basically is how we implement ALARA. Select the right transducer, start with a low output level, and obtain the best image possible by using focusing, receiver gain, and other imaging controls. If that is not adequate for diagnostic purposes, then increase the output level.

We can further implement ALARA by reducing total ultrasonic exposure time. That is, using our skill, experience, and knowledge of the patient, we can structure the exam to find and obtain useful images quickly. Recording and playing back parts or all of the exam for later measurement and analysis can further minimize the duration of the exposure.

Q. There are many different types of ultrasound systems with different controls and displays. Does ALARA change from system to system?

Some systems do not have an output control.
Different systems have different controls and displays.

A. ALARA remains the same. Keep ultrasound output "As Low As Reasonably Achievable." How we do that will change somewhat from system to system. For example, virtually all medical diagnostic ultrasound equipment has some type of acoustic output control. However, we may occasionally see a single purpose device that doesn't have an output adjustment. In this case, we practice ALARA by minimizing exposure time.

If the machine has an output control, we use it and the other controls to achieve ALARA. But remember, there are a variety of different types of intensity settings on ultrasound equipment, depending on the manufacturer's design. For example, some equipment may have a separate control on the keyboard or console that has discrete increments. Other equipment may have the intensity level adjustment accessed through the system presets. And, output settings may be displayed in a variety of different ways. For example, acoustic output may be expressed as a percentage of total power, in decibels, in intensity units of milliwatts per square centimeter, or in thermal or mechanical indices.

Acoustic output control:
percentage
decibel (dB)
Direct unit
(mW/cm^2 or mW)
Thermal index
Mechanical index

In addition to the technical aspect of ALARA, there's the philosophical aspect. This includes minimizing scan time, performing only required scans, and never compromising quality by rushing through an examination.

Q. We're responsible for patient care, and we must use diagnostic ultrasound prudently. What's the rule for prudent use?

A. We want the best diagnostic information with minimal exposure to the patient. And because the threshold at which ultrasound energy causes bioeffects is not known, our goal must be to adjust the intensity output of the equipment so as to get the most information at the lowest possible output level.

That’s what we mean by ALARA. Using settings that are “As Low As Reasonably Achievable” allow for the best quality ultrasound data for diagnosis.

Chapter Seven
The Output Display Standard

Issues addressed:

- Purpose of the Output Display Standard
- Mechanical Index (MI)
- Thermal Index (TI)
- Soft Tissue Thermal Index (TIS)
- Cranial Bone Thermal Index (TIC)
- Bone Thermal Index (TIB)
- When an Index is displayed
- What the Indices mean
- How to implement ALARA by using the Indices

Q. What is the output display standard?

Standard for Real–Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

A. One of many advances now being made in ultrasound equipment technology is the introduction of output display indices that relate to the potential for ultrasound bioeffects. These indices are specified in a standard developed in a cooperative effort by the National Electrical Manufacturers Association, the U.S. Food and Drug Administration, the American Institute of Ultrasound in Medicine, and many other medical and basic science societies.

Q. What is displayed?

A. Two types of indices may be displayed: a Thermal Index, or TI, which provides an estimate of the temperature increase; and a Mechanical Index, or MI, which provides an indication of the potential of nonthermal or mechanical bioeffects, such as cavitation.

Output Display
- Thermal Index (TI)
- Mechanical Index (MI)

Q. What is the purpose of the output display standard?

A. The goal of the output display standard is to make users aware of the actual output of their ultrasound equipment as it is being used. The TI and MI provide real-time information about the potential for bioeffects that can be used to help implement ALARA easily and efficiently. As users, we can quickly learn how different control settings change the indices. *We implement ALARA by obtaining needed information while keeping the indices, the potential for bioeffects, "as low as reasonably achievable."*

MI is a relative indicator of the potential for mechanical effects

Q. What is the Mechanical Index?

A. Scientific evidence suggests that mechanical, or nonthermal, bioeffects, like cavitation, are a threshold phenomenon, occurring only when a certain level of output is exceeded. However, the threshold level varies, depending on the tissue. The potential for mechanical effects is thought to increase as peak pressure increases, but to decrease as the ultrasound frequency increases. The Mechanical Index automatically accounts for both pressure and frequency. When interpreting the Mechanical Index, remember that it is intended to estimate the potential for mechanical bioeffects. The higher the index reading, the larger the potential. However, neither MI = 1, nor any other level, indicates that a bioeffect is actually occurring. We should not be alarmed by the reading, but we should use it to implement the ALARA principle.

Q. What is the Thermal Index?

	Scanned Mode	Unscanned Mode
Soft Tissue	TIS at Surface	TIS Small Aperture Large Aperture
Bone at Focus	TIS at Surface	TIB
Bone at Surface	TIC	TIC

A. Actually, there are three Thermal Indices that are used for different combinations of soft tissue and bone in the area to be examined. The purpose of the Thermal Indices is to keep us aware of conditions that may lead to a temperature rise whether at the surface, within the tissues, or at the point where the ultrasound is focusing on bone. Each Thermal Index estimates temperature rise under certain assumptions.

Three Thermal Indices
- Soft Tissue Thermal Index (TIS)
- Cranial Bone Thermal Index (TIC)
- Bone Thermal Index (TIB)

The Soft Tissue Thermal Index, known as TIS, provides information on temperature increase within soft homogeneous tissue. The Cranial Bone Thermal Index, called TIC, indicates temperature increase of bone at or near the surface, such as may occur during a cranial exam. The Bone Thermal Index, or TIB, provides information on temperature increase of bone at or near the focus after the beam has passed through soft tissue. For example, TIB is appropriate when focusing near fetal bone during a second or third trimester exam.

TI is a relative indicator of temperature increase

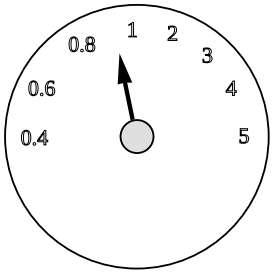
The Thermal Index is a relative indicator of temperature rise. Thus, a TI reading of 2 represents a higher temperature rise than a TI reading of 1. However, a TI of 1 should not be taken literally to mean an actual increase in temperature of 1°C, nor should a TI of 2 be taken to mean an increase of 2°C. The actual increase in temperature in the patient is influenced by a number of factors such as tissue type, blood perfusion, mode of operation, and exposure time. Those who developed the standard deliberately chose the term “Index” to avoid a literal association between the TI reading and actual temperature increase. The TI does, however, provide important information to the user: itindicates that the possibility for an increase in temperature exists, and it provides a relative magnitude that can be used to implement ALARA.

Q. How and when are the output indices displayed?

A. The output display must be located so as to be easily seen by the operator during an exam. An output display is not required if the transducer and system are not capable of exceeding an MI or TI of 1. However, if the transducer and system are capable of exceeding an MI or TI of 1, then it must display values as low as 0.4 to help the user implement ALARA.

No display of any index value is required if the transducer and system are not capable of exceeding an MI or TI of 1

The standard only requires that a single index be displayed at any one time. For some modes and application presets the user may be able to choose which index shall be displayed. For example, the Mechanical Index will appear for B-mode imaging if no other mode is active. A Thermal Index will be shown for all other modes, including modes where B-mode imaging is combined with something else such as M-mode, Doppler, or color flow imaging. The standard makes an exception for transducers that have no B-mode imaging. In that case, the Mechanical Index must be available in the Doppler mode.



A display of an index value as low as 0.4 is required if the transducer and system are capable of exceeding an MI or TI of 1.

The Mechanical Index is required for B-mode imaging because the mechanical effects, such as cavitation, are more likely to be significant than thermal effects. Similarly the rationale for using a Thermal Index in the other modes is that the potential for heating is the greater concern.

Q. Are there other system features required by the output display standard?

A. The output display standard requires manufacturers to provide default settings on their equipment. These settings establish the output level that will be used automatically at power-up, entry of new patient information, and a change from nonfetal to fetal application presets. Once the exam is under way, the user should adjust the output level as needed to achieve clinically adequate images while keeping the output index as low as possible.

Manufacturers are required to provide default settings

Q. Is it really that simple? All we need to know is the output index value?

A. Yes and no. A high index value does not always mean high risk, nor does it mean that bioeffects are actually occurring. There may be modifying factors which the index cannot take into account. But, high readings should always be taken seriously. Attempts should be made to reduce index values but not to the point that diagnostic quality is reduced.

The indices do not take *time* into account. Exposure time is an important factor users must keep in mind, especially if the index is in a

Minimizing exposure time will help reduce risk

range that might be considered high. Exposure time is the ultrasound exposure time at a particular tissue region. In all cases, minimizing ultrasound exposure time will help reduce risk.

Every patient is different. The tissue characteristics assumed in the formulas for the output display indices may differ significantly from the characteristics of the patient or exam type. Important characteristics we should consider include

- body size
- blood flow (or perfusion)
- the distance the organ of interest is from the surface
- where the bone is in relation to the beam axis and focal point, and
- factors, such as the presence or absence of fluid, that affect the attenuation of ultrasound.

Q. Tell us in more detail how to use the output display to help implement ALARA.

A. Let's look at the basic principles to follow. To begin, we determine if we are displaying the appropriate index. The Mechanical Index and Thermal Index are mode-specific, so that index selection is automatic. However, there may be cases when we can override the system's choice. When displaying a Thermal Index, we should ask four questions.

Thermal Index	Tissues	Typical Examinations
TIS	Soft tissue	Cardiac, first trimester fetal
TIB	Bone near focus	Second and third trimester fetal
TIC	Bone near surface	Transcranial

First, "Which Thermal Index is appropriate for the study we are performing—TIS, TIC, or TIB?" TIS is appropriate when imaging soft tissue and is used, for example, during first trimester fetal exams or in cardiac color flow imaging exams. TIC is used during transcranial examinations. And TIB is used when the focus is at or near bone and may be appropriate for second and third trimester fetal exams or certain neonatal cephalic exams.

The second question to ask is, "Are there modifying factors that might create either an artificially high or low reading?" These modifying factors include the location of fluid or bone and blood flow. For example, is there a low attenuation path so that the actual potential for local heating is greater than the TI display? This could be caused by an unusually long distance of amnioti, or other fluid through which the ultrasound must travel. Another example is that a highly perfused tissue area may have a lower temperature than indicated because blood flow transports heat away from the tissue.

Third, even if the index value is low, we should ask, “Can I bring it down?” Because there is uncertainty about how high is “too high,” we should always be alert to ways to adjust the system to reduce the indices. In many cases, an index reading can be reduced without decreasing the quality of the image.

Finally, we should ask, “How can we minimize ultrasound exposure time without compromising diagnostic quality?” This does not mean that we rush through the exam and take the chance of not getting information necessary for an accurate diagnosis. It means that we should get the best image possible with as little exposure time as necessary. There are a number of ways to reduce exposure time. For example, if the system does not disable pulsing during freeze frame, remove the transducer from the patient while working with a frozen image on the ultrasound display. Don’t scan obstetrical patients twice, once to obtain necessary diagnostic information and again to show images to the patient’s family and friends. Only scan areas of the body that are necessary to the diagnosis. And don’t use additional modes, such as Doppler or color, unless they benefit the diagnosis.

Q. Please give us some examples that show how the indices can be used to implement ALARA.

A. We will look at several examples. When we consider the Mechanical Index, the MI might be reduced by selection of appropriate transducer type, ultrasonic frequency, focal zone, and receiver gain.

Implementation of ALARA by using the Indices

Because there are three Thermal Indices, it is not so simple. As we go through the examples, remember the four questions we should ask related to the Thermal Index:

- Which TI?
- Are there modifying factors?
- Can we reduce the index value?
- Can we reduce the exposure time?

The first example is a color flow scan of the portal vein of the liver. TIS is the appropriate selection for nonobstetrical abdominal examinations. Possible modifying factors include capillary perfusion and body size. High perfusion in the imaged tissue will reduce thermal effects while conversely, a lack of perfusion may increase them. With increasing body size, extra tissue attenuation decreases mechanical and thermal effects at the focus. Also, when considering the focus for a soft tissue exam, remember that the potential for maximum heating might occur at the surface, at the focal point, or somewhere in between. For scanned modes, such as B-mode imaging and color flow, and for sector transducers, the maximum heating is usually close to the surface.

The second example is a pulsed Doppler cardiac exam. Again, TIS is the appropriate thermal index. The cooling effect of cardiac blood flow is a very important modifying factor. Actual increase in cardiac temperature is almost certainly less than the TIS indicates.

The next example is a second trimester pulsed Doppler fetal exam. In most cases with unscanned modes, like pulsed Doppler, the Thermal Index indicates heating near the surface. If bone is not present, maximum heating is likely to occur between the surface and the focus or sample volume, and the TIS is the relevant index. But, if bone is present, maximum heating will occur at the location of the bone. In this example, the TIB is the relevant index, although it will overestimate the actual temperature rise, unless the bone is located within the focal zone or sample volume.

The presence of fetal bone near the focal zone is the important factor. If the pulsed Doppler is used to measure umbilical blood flow, and we are sure there is no bone near the sample volume, the TIS is appropriate. However, because the transducer may be moved, it is usually best to make the more conservative choice and select TIB for all second and third trimester exams. Of direct concern are the fetus's developing neural tissues, such as the brain and spinal cord, that may be in a region of heated bone.

Other modifying factors include the type of overlying tissue, whether fluid or soft tissue, and the exposure time at the particular tissue region. The presence of fluid is important, because if more than half of the path is fluid-filled then the actual temperature rise may be higher than the TIB value displayed. To reduce the potential temperature rise, consider aiming the transducer to miss most of the bone structure without losing the region of interest, if possible, and optimize receiver gain and sample volume controls.

An additional consideration is whether heating is likely to be near the surface (in the mother's tissues) or deeper (in the fetal tissues). This depends mostly on whether we are using a scanned (2D or color) or unscanned (M-Mode or Doppler) mode. For scanned modes, heating tends to be near the surface; for unscanned modes, closer to the focal zone. However, in most cases where bone is along the beam axis, maximum heating occurs at the location of the bone.

Another example is a transcranial examination, where TIC is the appropriate Thermal Index. The presence of bone near the surface is the important factor in this case. To reduce the TIC reading, consider scanning through a thinner part of the skull, so that a lower output setting can be used.

The final example is a neonatal cephalic exam. The choice of Thermal Index depends on the location of bone. Generally, in an exam through the fontanelle TIB is the appropriate index because of the chance of focusing near the base of the skull. TIS might be appropriate if the focal zone will always be above the base of the skull. If the exam is through the temporal lobe, the temporal bone near the surface makes the TIC the appropriate index.

Conclusion

In more than three decades of use, there has been no report of injury to patients or to operators from medical ultrasound equipment. We in the ultrasound community want to keep that level of safety.

In the past, application-specific output limits and the user's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. Now, more information is available. The Mechanical and Thermal Indices provide users with information that can be specifically applied to ALARA. Mechanical and Thermal Indices values eliminate some of the guesswork and provide both an indication of what may actually be happening within the patient and what occurs when control settings are changed. These make it possible for the user to get the best image possible while following the ALARA principle and, thus, to maximize the benefits/risk ratio.